European Medicines Agency
Evaluation of Medicines for Human Use

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

The Committee for Medicinal Products for Human Use (CHMP) held its February plenary meeting from 18 to 21st February 2008.

CENTRALISED PROCEDURE

Initial applications for marketing authorisation

First pre-pandemic influenza vaccine receives positive opinion

The CHMP adopted a positive opinion by consensus recommending the granting of a marketing authorisation for the first pre-pandemic influenza vaccine, **Prepandrix** (split inactivated, adjuvanted, H5N1 influenza vaccine containing antigens from A/VietNam/1194/2004 NIBRG-14), from GlaxoSmithKline Biologicals S.A.

Pre-pandemic vaccines are vaccines prepared from influenza viruses with a pandemic potential that are intended for use before a pandemic is declared or during an officially declared influenza pandemic. EMEA review began on 24 January 2007 with an active review time of 189 days. A separate press release is available here.

In addition, the CHMP adopted a positive opinion by consensus recommending the granting of a marketing authorisation for **Pandemrix (**split inactivated, adjuvanted, H5N1 influenza vaccine containing antigens from A/VietNam/1194/2004 NIBRG-14), from GlaxoSmithKline Biologicals S.A. Pandemrix is a mock-up pandemic influenza vaccine, intended for the prevention of influenza during an officially declared pandemic influenza situation, once the pandemic viral strain has been included. It is the third mock-up pandemic influenza vaccine to receive a positive opinion from the Committee. EMEA review began on 21 February 2007 with an active review time of 161 days.

A question-and-answer document on mock-up pandemic influenza vaccines is available here.

Other positive opinions on initial applications for marketing authorisation

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

- **Adenuric** (febuxostat), from Ipsen Manufacturing Ireland, for the management of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis). EMEA review began on 27 September 2006 with an active review time of 188 days.

- **Mycamine** (micafungin sodium), from Astellas Pharma GmbH, for the treatment of invasive candidiasis; prophylaxis of candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia, and in adolescents aged 16 years or older and adults for the treatment of oesophageal candidiasis in patients for whom intravenous therapy is appropriate. The decision to use Mycamine should take into account a potential risk for the development of liver tumours (see SPC section 4.4). Mycamine should therefore only be used if other antifungals are not appropriate. EMEA review began on 24 May 2006 with an active review time of 203 days.

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- **Privigen** (Human Normal Immunoglobulin), from ZLB Behring AG, for use as replacement therapy in immunodeficiency and for immunomodulation in immune-mediated diseases. EMEA review began on 21 February 2007 with an active review time of 188 days.

- **Volibris** (ambrisentan), from Glaxo Group Limited, for the treatment of pulmonary arterial hypertension. Volibris is the 46th orphan medicine to receive a positive opinion. EMEA review began on 21 March 2007 with an active review time of 205 days.

Positive opinions for four biosimilars

The CHMP adopted four positive opinions by consensus for biosimilar medicinal products. **Ratiograstim** (filgrastim), from Ratiopharm GmbH**, Biograstim** (filgrastim), from CT Arzneimittel GmbH, **Tevagrastim** (filgrastim), from Teva Generics GmbH, and **Filgrastim ratiopharm** (filgrastim), from Ratiopharm GmbH, are intended for the treatment of neutropenia. All four medicines have been shown to be similar to Neupogen, the reference medicinal product already authorised in the European Union (EU), in the applied indication. EMEA review began on 21 February 2007 with an active review time of 209 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.

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

The EMEA has been formally requested by Celgene Europe, to re-examine the negative opinion for **Lenalidomide Celgene Europe** (lenalidomide) to be used for the treatment of anaemia due to myelodysplastic syndromes, adopted during the CHMP meeting on 21-24 January 2008.

Post-authorisation procedures

Extensions of indication and other recommendations

The CHMP adopted five positive opinions by consensus and one by majority (Forsteo) on applications for extensions of indication, adding new treatment options for the following previously approved medicines:

- **Abilify** (aripiprazole), from Otsuka Pharmaceutical Europe Ltd, to extend the indication to add the treatment of moderate to severe manic episodes in bipolar-I disorder and the prevention of a new manic episode in patients who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment. Abilify is currently authorised for the treatment of schizophrenia.

- **Alimta** (pemetrexed), from Eli Lilly Nederland B.V., to extend the indication to include first line treatment in combination with cisplatin of patients with locally advanced or metastatic non small cell lung cancer other than predominantly squamous cell histology. In addition, the existing second line monotherapy indication has been amended to exclude treatment of patients with predominantly squamous cell histology. Alimta is currently authorised in combination therapy for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma and as monotherapy for the treatment of patients with locally advanced or metastatic non small cell lung cancer after prior chemotherapy.

- **Forsteo** (teriparatide), from Eli Lilly Nederland B.V., to extend the indication to add the treatment of osteoporosis associated with sustained systemic glucocorticoid therapy in women and men at increased risk of fracture. Forsteo is currently indicated for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture.

- **Azomyr, Aerius and Neoclarityn** (desloratadine), from SP Europe, to extend the indication from chronic idiopathic urticaria to urticaria. Azomyr, Aerius and Neoclarityn are currently indicated for relief of symptoms associated with allergic rhinitis and chronic idiopathic urticaria.

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

Updated safety information

The Committee discussed cases of anaphylactic / hypersensitivity reactions observed in young adults in Canada following the use of **M-M-RVAXPRO** (in Canada called MMR-II) during a catch-up vaccination campaign in December 2007. The Committee recognised that M-M-RVAXPRO is contraindicated in patients with hypersensitivity to any measles, mumps or rubella vaccine, or to any of the excipients. The Product Information also contains warnings relating to patients with a history of hypersensitivity and anaphylactic / anaphylactoid reactions following the ingestion of egg.
In view of the cases observed in young adults, the Committee has requested the MAH (Sanofi Pasteur MSD) to update the Product Information to include the fact that adults and adolescents may potentially be at increased risk of anaphylaxis and anaphylactoid reactions, particularly those with a history of allergies.

Withdrawal

The EMEA has been formally notified by Actelion Ltd of its decision to withdraw the application for an extension of indication for the centrally authorised medicine **Zavesca** (miglustat). Zavesca was expected to be used for the treatment of neurological manifestations in patients with Niemann-Pick type C disease, an inherited neurodegenerative disease of childhood and adolescence. A separate press release with more information is available. The question-and-answer document will be available following the CHMP's March 2008 meeting.

OTHER INFORMATION ON THE CENTRALISED PROCEDURE

Lists of Questions

The Committee adopted three Lists of Questions on initial applications (including two under the mandatory scope, and one under the optional scope) and a List of Questions on "line extension" application (in accordance with Annex II of Commission Regulation (EC) No. 1085/2003).

Consultation procedure on an ancillary substance in a medical device

The Committee also adopted a positive opinion by consensus on **Human Albumin Solution** in the context of its use as ancillary medicinal substance in **Reproductive Media Products containing Human Tissues/Plasma** from **Irvine Scientific**. The applicant/Notified Body for the consultation procedure is **National Standards Authority of Ireland (NSAI)**. EMEA review began on 19 July 2007 with an active review time of 176 days.

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 January 2008 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 January 2008 CHMP plenary meeting are provided in **Annex 4**.

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 5**.

REFERRAL PROCEDURES

Referral procedure concluded

The CHMP concluded a referral procedure by majority for **Coxtral gel**, 3% gel, (nimesulide) from Zentiva A.S., recommending the refusal of the granting of marketing authorisations and the suspension of the granted marketing authorisations, where appropriate. Coxtral gel is indicated for the symptomatic relief of pain associated with sprains and acute traumatic tendinitis. The procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC, as amended) because of disagreement between Member States relating to the efficacy of the medicine. In its scientific assessment, the CHMP concluded that the therapeutic equivalence had not been adequately demonstrated and that therefore the benefit-risk profile of Coxtral gel is considered unfavourable.

Concluding the re-examination of a referral procedure for **Eformax**, inhalation powder, (formoterol fumarate), from IVAX Pharmaceuticals UK, the CHMP confirmed by consensus its previous recommendation to refuse the granting of the marketing authorisations and the suspension of the granted marketing authorisation where appropriate. Eformax is indicated for the treatment of broncho-obstructive symptoms in asthmatic patients when treatment with corticosteroids is not sufficient. The procedure was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC, as amended) because of disagreement between Member States relating to the safety and efficacy of the medicine. The CHMP concluded that the therapeutic equivalence to the reference medicinal product could not be demonstrated and that therefore the benefit-risk profile of Eformax is considered unfavourable.

Referral procedures started

The CHMP started a referral procedure for **Lisonorm,** 5mg amlodipine/ 10 mg lisinopril tablets, (amlodipine/lisinopril), from Gedeon Richter, because of disagreement between the Member States on the grounds for approval of this medicine. Lisonorm is indicated as substitution therapy for patients with blood pressure adequately controlled with lisinopril and amlodipine given concurrently at the same dose level. The referral was initiated under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC, as amended).

The CHMP started a referral procedure for **Augmentin** (amoxicillin/clavulanic acid), from GSK, because of divergence in the product information. Augmentin is indicated for the treatment of bacterial infections. The procedure was initiated under Article 30 of the Community code on human medicinal products (Directive 2001/83/EC, as amended).

Review procedures under Article 107

The European Commission has referred the positive opinion for **nimesulide-containing medicines** back to the CHMP. This opinion, which was issued by the CHMP on 20 September 2007 under Article 107, recommended the maintenance of the marketing authorisations for these medicines, subject to restricted use. It followed the suspension of the marketing authorisation for nimesulide in Ireland, due to concerns over serious liver problems. The Commission has requested that the CHMP reconsider its position in the light of further cases of suspected liver injury and re-evaluate the recommended risk minimisation measures. The outcome is expected in the coming months and will be published on the Agency's website.

MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 26th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 18-20 February 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 30th January-1st February 2008. For further details, please see **Annex 6**.

Documents prepared by the CHMP Working Parties adopted during the February 2007 CHMP meeting are listed in **Annex 7**.

UPCOMING MEETINGS FOLLOWING THE FEBRUARY 2008 CHMP PLENARY MEETING

- The 42nd meeting of the CHMP will be held at the EMEA on 17-19 March 2008.
- The next Name Review Group meeting will be held at the EMEA on 1st April 2008.
- The 27th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 17-19 March 2008.

ORGANISATIONAL MATTERS

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

- The appointment of Mr. Hemmings from United Kingdom as the fifth Co-opted CHMP member, with expertise in the area of Medical Statistics (clinical trial methodology /epidemiology).
- The re-election of Dr. Trouvin as Chair of the Biologics Working Party.
- The re-election of Dr. Cichutek as Chair of the Gene Therapy Working Party and election of Dr. Galli as Vice Chair.
- The re-election of Dr. van Zwieten Boot as Chair of the Efficacy Working Party and Dr. Jonsson as Vice-Chair.
- The agreement to organise a second meeting for experts appointed by the CHMP and European Commission respectively on harmonisation of their respective draft guidelines on the evaluation of non-clinical and clinical data on the medicinal substances contained in drug-eluting stents, to be held on 10th March 2008.
- Follow-on discussion with regard to biomarker qualification process. The Committee adopted a reflection paper for the establishment of the EMEA qualification process of innovative drug development methods (such as the use of new biomarkers), which is foreseen for publication at the end of March 2008.
- Follow-on discussion with regard to the reflection paper On Benefit-Risk Assessment Methods in the Context of the Evaluation of Marketing Authorisation Applications of Medicinal Products for Human Use (EMEA/CHMP/15404/2007).
- Discussion on the proposed draft Concept Paper for ICH Guideline on Development and Manufacture of Drug Substances.
- Preliminary discussion regarding prioritisation of tasks the CHMP would like to further develop during the next three years. This month the discussion focused on Advanced Therapies, Antimicrobial Resistance, Microbicides, ongoing revision of the SPC guideline, evaluation of risk/benefit and a revised publication policy for members of scientific Committees.
- A CMD(h) request to ask the Vaccine Working Party to comment on the core SPC for Influenza Vaccines and the inclusion of quantity of ovalbumin in the SPC.
- Discussion on the development of Annex I (Technical Requirements) for Advanced Therapy Medicinal Products. The Committee adopted their proposal for revision of Annex I, which will now be transmitted to the European Commission for consideration.
- The adoption of a new assessment report template for quality type II variations.
- A one-year overview of the Rapporteurship appointment procedure following the implementation of the CHMP Rapporteur/Co-Rapporteur appointment: Principles, Objective Criteria and Methodology.

- Discussion and adoption of the minor amendment made to the published procedure for coordinating GCP inspections requested by the EMEA.
- Discussion on a pilot testing of the simplified bi-weekly PSUR for pandemic vaccines.
- Follow-on discussion on the European Network of Centres of Pharmacovigilance and Pharmacoepidemiology (ENCePP) project. A second meeting with all ENCePP centres is scheduled on 18 April 2008. Topics that will be discussed include: the draft Working Model, the 4 Working Groups to be put in place, the establishment of the ENCePP Implementation Advisory Group, and the promotion of IMI pharmacovigilance calls.

PROCEDURAL ANNOUNCEMENT

- Renewal applications

MAHs are reminded that **renewal applications** have to be submitted **at least 6 months before** expiry of the marketing authorisation. MAHs should check the expiry date of their marketing authorisation and plan for the submission of the renewal application in advance of the 6-month legal deadline.

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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

ANNEX 1 TO CHMP MONTHLY REPORT FEBRUARY 2008

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	6	0	0	0	2	1	2	11	679
Positive opinions	3	2	0	0	6	0	2	13	443
Negative opinions[1]	0	0	0	0	0	0	1	1	19
Withdrawals prior to opinion	0	0	0	0	3	0	0	3	119
Marketing authorisation granted by the Commission	3	1	0	0	0	0	0	4	421

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)	0	11
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 FEBRUARY 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

ANNEX 2 TO CHMP MONTHLY REPORT FEBRUARY 2008

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)	182	5384
Type II Variations (positive opinions)	145	3789
Type II Variations (negative opinions)	0	10
Annex II Applications (positive opinions)	14	183
Annual Re-assessment (positive opinions)	3	-
Opinion for renewals of conditional MA's (positive opinions)	0	2
5 Year Renewals (positive opinions)	2	-

Opinions for Type II Variation applications	
Number of Opinions	**Outcome**
9 Extensions of indication	9 Positive opinion
30 SPC changes	30 Positive opinions
46 Quality changes	46 Positive opinions

Opinions for Annual Re-Assessment applications		
Name of Medicinal Product (INN) MAH	**Outcome**	**Comments**
Aptivus (tipranavir) Boehringer Ingelheim	Positive Opinion adopted	exceptional circumstances are being lifted

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**
N/A	N/A	N/A

ANNEX 3 TO CHMP MONTHLY REPORT FEBRUARY 2008

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

Invented Name	N/A
INN	N/A
Marketing Authorisation Holder	N/A
Proposed ATC code	N/A
Indication	N/A
CHMP Opinion date	N/A
Marketing Authorisation Date	N/A

OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION: UPDATE SINCE THE JANUARY 2008 CHMP MEETING

Active substance	**Sponsor/applicant**	**EU Designation Number & Date of Orphan Designation**	**Designated Orphan Indication**
Azacitidine	Pharmion Ltd.	EU/3/01/084	Treatment of myelodysplastic syndromes

ANNEX 5 TO CHMP MONTHLY REPORT FEBRUARY 2008

INVENTED NAME REVIEW GROUP (NRG)

	February 2008		2008	
	Accepted	Rejected	Accepted	Rejected
Proposed invented names[1]	18	14	18	14
Justification for retention of invented name *[2]	3	1	3	1

*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]One justification for retention of a proposed invented name has been postponed to the next NRG meeting

[2] Two proposed invented name requests have been postponed to the next NRG meeting

	January 2008		2008	
	Accepted	Rejected	Accepted	Rejected
Total number of objections raised	21	22	21	22
Criterion - Safety concerns				
Similarity with other Invented name	18	15	18	15
Conveys misleading therapeutic/pharmaceutical connotations	1	0	1	0
Misleading with respect to composition	0	0	0	0
Criterion - INN concerns				
Similarity with INN	1	1	1	1
Inclusion of INN stem	0	1	0	1
Criterion - Other public health concerns				
Unacceptable qualifiers	1	3	1	3
Conveys a promotional message	0	2	0	2
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	0	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 6 TO CHMP MONTHLY REPORT FEBRUARY 2008

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

	1995 - 2007	2008	Overall Total
Scientific Advice	887	29	916
Follow-up to Scientific Advice	171	7	178
Protocol Assistance	198	8	206
Follow-up to Protocol Assistance	90	4	94
	1346	**48**	**1394**

OUTCOME OF THE FEBRUARY 2008 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	Prevention or delay to onset of severe oral mucositis	X						X	
Chemical	Treatment of of type 2 diabetes mellitus	X				X	X	X	
Biological	Treatment of non small cell lung cancer	X						X	
Chemical	Treatment of glioma	X					X		
Chemical	Treatment of cutaneous T-cell lymphoma		X			X		X	X
Chemical	Treatment of T-cell Lymphoma		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 anaemia in patients with chronic renal failure			X				X	
Biological	Treatment of critical limb ischemia			X		X	X		
Chemical	Treatment of severe sepsis			X				X	
Biological	Treatment of meningococcal septicaemia				X			X	
Biological	Prevention of Pseudomonas aeruginosa infection			X				X	
Chemical	Treatment of benign prostatic hyperplasia and reduction in the risk of acute urinary retention	X				X			
Chemical	Treatment of acute pain	X						X	
Biological	Treatment of cervical spinal cord injury	X				X	X	X	
Chemical	Treatment of multiple sclerosis	X						X	
Chemical	Treatment of asthma and COPD			X				X	
Biological	Treatment of ligneous conjunctivitis		X				X	X	
Biological	Treatment of diabetic macular oedema	X					X	X	
Biological	Treatment of growth hormone deficiency	X				X	X	X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 11 Scientific Advice letters, 3 Protocol Assistance letters, 5 Follow-up Scientific Advice and 1 Follow-up Protocol Assistance letter were adopted at the 18-21 February 2008 CHMP meeting.

New requests for Scientific Advice Procedures

The Committee accepted 27 new Requests for which the procedure started at the SAWP meeting held on 30 January – 1 February 2008. The new requests are divided as follows: 18 Initial Scientific Advice, 4 Follow-up Scientific Advice, 2 Initial Protocol Assistance and 1 Follow-up Protocol Assistance.

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

BIOLOGICS WORKING PARTY (BWP)

Reference number	Document	Status[3]
EMEA/10470/2008	Revision 4 of the Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary products	Adopted for transmission to DG Enterprise
EMEA/CHMP/BWP/ 466097/2007	Concept paper on a guideline on the chemical and pharmaceutical quality documentation concerning biological investigational medicinal products in clinical trials	Adopted
EMEA/CHMP/BWP/ 580136/2007	BWP report Interferons and neutralising antibodies	Adopted

CHMP PHARMACOGENOMICS WORKING PARTY (PgWP)

Reference number	Document	Status[3]
EMEA/70877/2008	PgWP comments on the European Society of Human Genetics Policy Paper	Adopted
EMEA/49246/2008	PgWP comments on the EFPIA document "Key messages Surrounding Pharmacogenetics"	Adopted

QUALITY WORKING PARTY (QWP)

Reference number	Document	Status[3]
EMEA/CHMP/CVMP/ QWP/28271/2008	Reflection Paper on Water for Injection Prepared by Reverse Osmosis	Adopted
EMEA/CHMP/CVMP/ QWP/76509/2008	Question-and-answer document on Glycerol (Glycerin) contamination	Adopted and now pending CVMP adoption.
EMEA/CHMP/SWP/QWP /4446/2000	Guideline on the Specification Limits for Residues of Metal Catalysts of Metal Reagents	Adopted

SAFETY WORKING PARTY (SWP)

Reference number	Document	Status[3]
EMEA/CHMP/SWP/ 488313/2007	Revision of the Note for Guidance on Repeated Dose Toxicity	Adopted for 3-month public consultation.
EMEA/CHMP/SWP/QWP /4446/2000	Guideline on the Specification Limits for Residues of Metal Catalysts of Metal Reagents	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”).

EFFICACY WORKING PARTY (EWP)

Reference number	Document	Status[3]
CPMP/EWP/240/95 Rev. 1	Guideline on fixed-combination medicinal products	Adopted for 3-month public consultation.
EMEA/CHMP/EWP/ 12052/2008	Concept Paper on the Harmonisation and Update of the Clinical Aspects in the Authorised Conditions of Use for Radiopharmaceuticals and other Diagnostic Medicinal Products	This concept paper is undergoing administrative revision and is anticipated to be released for public consultation in May 2008.