European Medicines Agency
*Evaluation of Medicines for Human Use*

London, 27th November 2007
EMEA/522109/2007

**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**
**NOVEMBER 2007 PLENARY MEETING**
**MONTHLY REPORT**

The Committee for Medicinal Products for Human Use (CHMP) held its November plenary meeting from 12-15 November 2007.

## CENTRALISED PROCEDURE

### Initial applications for marketing authorisation

The CHMP adopted two positive opinions by consensus on initial marketing authorisation, recommending the granting of a marketing authorisation for the following medicinal products:

- **Ivemend** (fosaprepitant), from Merck Sharp & Dohme, for the prevention of chemotherapy-induced nausea and vomiting. EMEA review began on 24 May 2006 with an active review time of 197 days.

- The Committee recommended the granting of a conditional marketing authorisation for **Isentress** (raltegravir), from Merck Sharp & Dohme Ltd, for use in combination with other antiretroviral medical products for the treatment of human immunodeficiency virus (HIV-1) infection in treatment-experienced adult patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. Isentress has been evaluated by accelerated assessment. EMEA review began on 23 May 2007 with an active review time of 141 days.

Negative opinion

The CHMP adopted a negative opinion by consensus recommending the refusal of a marketing authorisation for **CIMZIA** (certolizumab pegol), from UCB S.A. CIMZIA was intended to be used for reducing signs and symptoms and maintaining clinical response in patients with active Crohn's disease. EMEA review began on 24 May 2006 with an active review time of 202 days.

A separate question-and-answer document explaining the grounds for the negative opinion for CIMZIA is available on the EMEA website.

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.

'Informed consent' application

The Agency adopted a positive opinion for **Tesavel** (sitagliptin phosphate monohydrate), from Merck Sharp & Dohme, for which an 'informed consent' application was submitted. The reference product for this application is Januvia, also from Merck Sharp & Dohme (see above). Tesavel is recommended in the treatment of type-II diabetes mellitus in combination with either metformin, sulphonylurea, in certain patients with a PPARγ agonist (i.e. thiazolidinedione), or in triple combination treatment with metformin and a sulphonylurea, to improve glycaemic control. EMEA review began on 16 September 2007 with an active review time of 60 days.

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

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

Following the re-examination of the negative opinion adopted on 19 July 2007, the CHMP confirmed its previous position and adopted a final negative opinion for **Natalizumab Elan Pharma** (natalizumab), from Elan Pharma, to be used to treat moderate to severe active Crohn's disease in patients who had an inadequate response to or could not take conventional treatments for the disease and who have evidence of active inflammation. Natalizumab was proposed to be used alone or in combination with other medicines for Crohn's disease.
A separate question-and-answer document with more detailed information about the re-examination procedure is available on the EMEA website.

Withdrawal

The EMEA has been formally notified by INFAI Institut für biomedizinische Analytik & NMR-Imaging GmbH, of its decision to withdraw its application for a centralised marketing authorisation for the medicinal product **Gastromotal** (1-$^{13}$C-caprylic acid). Gastromotal was expected to be used to diagnose delayed stomach emptying in patients with stomach problems. A separate press release and question-and-answer document with more information are available.

## Post-authorisation procedures

Extensions of indication and other recommendations

The CHMP gave six positive opinions by consensus on applications for extensions of indication, adding new treatment options for the following previously approved medicines:

- **Angiox** (bivalirudin), from The Medicines Company UK Ltd, to extend the indication to include treatment, in combination with aspirin and clopidogrel, of adult patients with acute coronary syndromes (unstable angina/non-ST segment elevation myocardial infarction) planned for urgent or early intervention. Angiox is currently authorised as an anticoagulant in patients undergoing percutaneous coronary intervention (PCI).

- **Avastin** (bevacizumab), from Roche Registration Ltd, to extend the indication to include the treatment of advanced or metastatic renal cell cancer in combination with interferon alfa-2a. Avastin is currently authorised for first-line treatment of patients with metastatic carcinoma of the colon or rectum, metastatic breast cancer, and unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology.

- **Caelyx** (doxorubicin), from SP Europe, to extend the indication for the treatment of patients with relapse multiple myeloma in combination with Velcade (bortezomib). Caelyx is currently authorised for patients with metastatic breast cancer, advanced ovarian cancer and AIDS-related Kaposi's sarcoma.

- **Humira** (adalimumab), from Abbott Laboratories, to add the indication of treatment of adult patients with moderate to severe chronic plaque psoriasis. Humira is currently indicated in rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's disease.

- **Januvia** and **Xelevia** (sitagliptin phosphate monohydrate) from Merck Sharp & Dohme Ltd, to extend the indication to include a dual combination treatment of sitagliptin and a sulphonylurea and to include a triple combination treatment of sitagliptin with metformin and a sulphonylurea. Januvia and Xelevia are currently authorised in the treatment of type-II diabetes mellitus in combination with either metformin or, in certain patients, with a PPARγ agonist (i.e. thiazolidinedione) to improve glycaemic control.

Re-examination procedure (Type II variations) under Article 6(9) of Commission Regulation (EC) No 1085/2003

The EMEA has been formally requested by Actelion Ltd to re-examine the negative opinion for the extension of indication for **Zavesca** (miglustat), to include the treatment of neurological manifestations in patients with Niemann-Pick type C disease, an inherited neurodegenerative disease of childhood and adolescence, adopted during the CHMP meeting on 15-18 October 2007.

New safety information

The Committee agreed on the provisional inclusion of warnings concerning the risk of severe hypersensitivity reactions in the prescribing and patient information for **Protelos/Osseor** (strontium ranelate), as an urgent measure. The warnings relate to drug rash with eosinophilia systemic symptoms (DRESS) and Stevens Johnson-Syndrome. A separate press release and a question-and-answer document with more information are available on the EMEA website.

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

## OTHER INFORMATION ON THE CENTRALISED PROCEDURE

### Lists of questions

The Committee adopted eight lists of questions on initial applications including two duplicate licences (two under the mandatory scope, and six under the optional scope) and two lists of questions on 'line extensions' applications, one being a duplicate licence (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 October 2007 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 October 2007 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 eight referral procedures by consensus under Article 29 of the Community code on human medicinal products (Directive 2001/83/EC as amended). 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. The products concerned are:

- **Eformax** (formoterol fumarate), from IVAX Pharmaceuticals UK, indicated for the treatment of broncho-obstructive symptoms in asthmatic patients when treatment with corticosteroids is not sufficient. The procedure was initiated as a result of safety and efficacy concerns. The CHMP concluded that equivalent safety and efficacy to the reference medicinal product could not be

demonstrated and recommended the refusal of the granting of the marketing authorisations and the suspension of the granted marketing authorisation where appropriate.

- **Menitorix** (Hib/MenC conjugate vaccine), from GSK Bio, indicated for the prevention of invasive diseases caused by *Haemophilus influenzae* type b (Hib) and *Neisseria meningitides* group C (MenC) in infants from the age of 2 months and children up to the age of 12 years. The procedure was initiated because of a disagreement between Member States over licensing. The CHMP recommended granting the marketing authorisation with a commitment to submit the results from the long-term antibody persistence data from the ongoing studies with Menitorix to the relevant National Competent Authorities for assessment.

- **Simvastatin Krka** (simvastatine), from Krka Sverige AB, indicated for the treatment of hypercholesterolaemia and cardiovascular prevention. The procedure was initiated as a result of bioequivalence and pharmacokinetic concerns. The CHMP concluded that the application does not satisfy the criteria for authorisation in respect of efficacy, and recommended the refusal of the granting of marketing authorisations and the suspension of the granted marketing authorisation where appropriate.

- **Fentastad, Fentador, Matripain, Matrigesic** and **Fentrans** (fentanyl), from STADA Arzneimittel AG, indicated for the treatment of severe cancer pain which can be adequately managed only with opioid analgesics. The procedure was initiated because of efficacy, safety and bioequivalence concerns. The CHMP concluded that the application does not satisfy the criteria for authorisation in respect of quality, safety, and efficacy, and recommended the refusal of the granting of marketing authorisations and the revocation of the granted marketing authorisations, where appropriate.

**Referral procedures started**

The CHMP started referral procedures under Article 29 of Directive 2001/83/EC as amended for **Anya film-coated tablet** (levonorgestrel/ethinyl estradiol), from Wyeth AB, and for **Alvesco and associated names** (ciclesonide), from Altana Pharma. The procedures were initiated because of disagreement between Member States and the company over the summary of product characteristics.

The CHMP initiated three procedures under Article 6(12) of Commission Regulation (EC) No 1084/2003 for **moxifloxacin-containing medicinal products**, from Bayer Healthcare AG and Bayer Vital GmbH, because of disagreement between Member States on the extension of the therapeutic indication of moxifloxacin to include pelvic inflammatory disease.

A harmonisation referral under Article 30 of Directive 2001/83/EC was triggered by the European Commission for **Zoloft and associated names** (sertraline), from Pfizer, to promote harmonisation of the authorisations granted for this medicinal product.

**Review procedures under Article 107**

The CHMP finalised a procedure under Article 107, initiated as a result of the evaluation of pharmacovigilance data, for **carisoprodol-containing medicinal products**, intended mainly for the short-term treatment of acute lower back pain. This review was initiated following the decision to withdraw the marketing authorisation in Norway as of May 2008, due to concerns over increased risk of abuse or addiction, as well as intoxication and events related to psychomotor impairment. The CHMP concluded that the risks of these medicines outweigh their benefits and recommended the suspension of the marketing authorisations. A separate press release and a question-and-answer document with more detailed information are available on the EMEA website.

The CHMP initiated two procedures under Article 107 for:

- **Lumiracoxib-containing medicinal products**, intended for the treatment of osteoarthritis further to the notification by the UK who were considering the suspension of the marketing authorisation due to possible increased risk of hepatotoxic adverse events at the 100mg dose. Further to an oral hearing with the marketing authorisation holder and on the basis of currently available data, the CHMP

requested additional information in order to allow it to proceed with its review at the December 2007 meeting.

- **Aprotinin-containing medicinal products,** used for the prophylactic use to reduce perioperative blood loss and the need for blood transfusion in those patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft (CABG) surgery. This was further to the decision by Germany on 5 November 2007 to suspend all nationally authorised products containing aprotinin for intravenous use due to an increased risk of mortality in the aprotinin arm of the BART study. The marketing authorisation holder for Trasylol and Trasynin, Bayer Healthcare, has suspended the marketing of the products worldwide. A separate press release and a question-and-answer document with more detailed information are available on the EMEA website.

## MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES - HUMAN

The CHMP noted the report from the 23rd CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 12-14 November 2007. For further details, please see the relevant press release on the CMD(h) website under the heading Press Releases: http://www.hma.eu/

The CHMP also noted that a new list of medicinal products for which harmonised SPCs should be drawn up, in accordance with Article 30(2) of Directive 2001/83/EC, as amended had been agreed by the CMD(h) and published on the CMD(h) website for an eight week period for public consultation. The draft list of products for SPC harmonisation is available here.
*Any comments on the list of medicinal products for SPC harmonisation should be sent to the CMD(h) Secretariat (sonia.ribeiro@emea.europa.eu) by 2 January 2008, coordinated where possible by trade associations.*

## 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 29-31 October 2007. For further details, please see **Annex 6**.

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

## UPCOMING MEETINGS FOLLOWING THE OCTOBER 2007 CHMP PLENARY MEETING

- The 39th meeting of the CHMP will be held at the EMEA on 10-13 December 2007.
- The next Name Review Group meeting will be held at the EMEA on 10th December 2007.
- The 24th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 10-12 December 2007.

## ORGANISATIONAL MATTERS

The main topics addressed during the November 2007 CHMP meeting related to:

- Discussion on the criteria for one additional 5-year renewal for centrally authorised products following the 3-month public consultation initiated back in June 2007. The Committee confirmed their position on most of the proposed criteria, with some minor exceptions. The document will be published on the EMEA website in December 2007.
- Discussion of eligibility requests to the centralised procedure for “Over the Counter” medicinal products.
- The adoption of the revision of Volume 9A of The Rules Governing Medicinal Products in the European Union taking into consideration amendments to Chapter I.3 on Risks Management Plan to implement the new Paediatric Legislation; additional guidance was added with regard to biological products and product traceability; additional explanation as to why reporting of lack of efficacy and suspected transmission of an infectious agent is required for vaccines was also added.

- The adoption of the draft Pharmacovigilance Inspection Programme for Centrally Authorised Products for 2008-2011 as well as procedures for coordinating and reporting Pharmacovigilance Inspections requested by the Committee.
- Initial discussion on the draft revised variations regulation.
- Follow-on discussion on the draft implementation plan / innovative drug development approaches, based on the final report from the EMEA/CHMP-think tank group on innovative drug development.
- Follow-on discussion on the Advanced Therapies Regulation and consequences for the CHMP.
- The finalisation of ICH Topic E 15 Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories which was adopted by the Committee.
- The report on the ICH meeting held in Yokohama on 28 October – 1 November 2007.
- Discussion on the EMEA database on pathogenic agents in biological warfare that compiled scientific information concerning pathogenic agents, which might be used in biological warfare, including the existence of vaccines and other medicinal products available to prevent, or to treat the effects of such agents. Such database will be made publicly available in the near future.
- The final report from the HIV prophylactic vaccine ad-hoc group as well as feedback from the WHO-ANRS meeting held on the 5-6 September 2007.
- Initial discussion on microbicides for HIV prevention.
- The draft agenda for one-day Workshop on Paediatric Regulation to be held on 30 November.
- A CHMP Training on Gene Therapy to be held on 6-7 December 2007.
- Presentation of a draft Action Plan for further surveillance actions coordinated by the QWP on mesilates actives substance for Human Use.
- The request from the European Commission on the current use of Red 2G (E128) as colouring matter in medicinal products following the suspension of the use of Red 2G as colouring matter in food.
- A few SAG meetings scheduled over the coming months (SAG Clinical Neuroscience meeting to be held on the 20th November 2007; SAG Diagnostic meeting to be held on the 3rd December 2007; SAG Diabetes and Endocrinology meeting to be held on the 11th January 2008 and SAG HIV/Viral Diseases meeting to be held on 28th February 2007).

## PROCEDURAL ANNOUNCEMENT

**Changes to the provision of final language versions of the product information for medicinal products for human use (pilot phase for variations)**

The Agency has undertaken a process improvement exercise in 2007 to review the process, increase efficiency and reduce the administrative burden which is expected to benefit not only the EMEA but, also, applicants. As an outcome, the EMEA has tested an improved process for the provision of final product information in PDF format in a pilot phase for a number of procedures and with a number of applicants. In this process, applicants provided the final Annexes as PDF documents to the EMEA and the experience has been positive. As of 1 December 2007, the voluntary pilot phase is therefore extended to all variations and applicants are encouraged to gain experience with the improved process. The EMEA will review its experience with the revised process after 6 months and consider whether any further amendments/process improvements should be made. Details on the improved process and on how to provide the final product information in PDF is provided **here** as well as on the EMEA website (Human Medicines - Quality Review of Documents (QRD)/product information templates)

**Timetables for all applications**

In the framework of the internal process improvement activities and to enhance the transparency with the EMEA's stakeholders, the website has been updated in connection with the submission dates. For the first time the full timetables for all applications (Full and Extensions applications, Type II Variations, Renewals and Referrals) are presented. The updated dates can be found under the topic "Submission dates/Procedural timetables".
http://www.emea.europa.eu/htms/human/submission/submission.htm

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 NOVEMBER 2007

## PRE-AUTHORISATION: MARKETING AUTHORISATION APPLICATIONS

| Activity | 2007 | | | | | | | | 1995 onwards |
|---|---|---|---|---|---|---|---|---|---|
| | Optional Scope | | | | Mandatory scope | | | Total | Overall total |
| | NAS | Significant innovation | Interest of Patients | Generics | Biotech | Indications | Orphans | | |
| Applications for MA submitted | 35 | 5 | 0 | 6 | 17 | 8 | 9 | 80 | 655 |
| Positive opinions | 18 | 4 | 0 | 4 | 13 | 8 | 5 | 52 | 431 |
| Negative opinions[1] | 1 | 0 | 0 | 0 | 2 | 1 | 0 | 4 | 16 |
| Withdrawals prior to opinion | 4 | 1 | 0 | 0 | 5 | 0 | 2 | 12 | 115 |
| Marketing authorisation granted by the Commission | 21 | 1 | 0 | 1 | 9 | 6 | 8 | 46 | 411 |

## PRE-AUTHORISATION: SCIENTIFIC SERVICES

| Activity (submissions) | 2007 | 1995 onwards |
|---|---|---|
| Compassionate use applications | 0 | 0 |
| Art. 58 applications | 1 | 4 |
| Consultation for medical devices[2] | 1 | 3 |
| PMF (Click here for a list of PMF certifications) | 2 | 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 NOVEMBER 2007 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 | 2007 | Overall total 1995 onwards |
|---|---|---|
| Type I Variations (positive notifications) | 927 | 5123 |
| Type II Variations (positive opinions) | 732 | 3594 |
| Type II Variations (negative opinions) | 2 | 10 |
| Annex II Applications (positive opinions) | 27 | 169 |
| Annual Re-assessment (positive opinions) | 21 | - |
| Opinion for renewals of conditional MA's (positive opinions) | 2 | 2 |
| 5 Year Renewals (positive opinions) | 46 | - |

| Opinions for Type II Variation applications | |
|---|---|
| **Number of Opinions** | **Outcome** |
| 6 Extensions of indication | 6 Positive opinions |
| 32 SPC changes | 32 Positive opinions |
| 32 Quality changes | 32 Positive opinions |

| Opinions for Annual Re-Assessment applications | | |
|---|---|---|
| **Name of Medicinal Product (INN) MAH** | **Outcome** | **Comments** |
| **Velcade** (bortezomib) Janssen-Cilag International NV | Positive Opinion adopted | The product remains under exceptional circumstances. |
| **Evoltra** (clofarabine) Bioenvision Limited | Positive Opinion adopted | The product remains under exceptional circumstances. |

| **Opinion for renewals of conditional MA's** | | |
|---|---|---|
| **Name of Medicinal Product (INN)<br>MAH** | **Outcome** | **Comments** |
| **Prezista** (darunavir)<br>Tibotec | Positive Opinion adopted | N/A |

| **Opinions for 5-Year Renewal applications** | | |
|---|---|---|
| **Name of Medicinal Product (INN)<br>MAH** | **Outcome** | **Comments** |
| **Viramune** (nevirapine)<br>Boehringer Ingelheim International GmbH | Positive Opinion adopted | The Committee agreed that a further 5-year renewal would be required |
| **Viracept** (nelfinavir)<br>Roche Registration Ltd, | Positive Opinion adopted | The Committee agreed that a further 5-year renewal would be required |

**ANNEX 3 TO CHMP MONTHLY REPORT NOVEMBER 2007**

**MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE OCTOBER 2007 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 OCTOBER 2007 CHMP MEETING

| **Active substance** | **Sponsor/applicant** | **EU Designation Number & Date of Orphan Designation** | **Designated Orphan Indication** |
|---|---|---|---|
| Anti-epidermal growth factor receptor antibody h-R3 | Theraloc | Oncoscience AG | EU/3/04/220 |

**ANNEX 5 TO CHMP MONTHLY REPORT NOVEMBER 2007**

**INVENTED NAME REVIEW GROUP (NRG)**

| | November 2007 | | 2007 | |
|---|---|---|---|---|
| | Accepted | Rejected | Accepted | Rejected |
| Proposed invented names[1] | 16 | 11 | 148 | 143 |
| Justification for retention of invented name *[2] | 4 | 3 | 25 | 28 |

*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] Two proposed invented name requests have been postponed to the December NRG meeting

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

| | November 2007 | | 2007 | |
|---|---|---|---|---|
| | Accepted | Rejected | Accepted | Rejected |
| Total number of objections raised | 24 | 14 | 267 | 236 |
| **Criterion - Safety concerns** | | | | |
| Similarity with other Invented name | 20 | 7 | 220 | 172 |
| Conveys misleading therapeutic/pharmaceutical connotations | 1 | 0 | 8 | 1 |
| Misleading with respect to composition | 0 | 0 | 7 | 1 |
| **Criterion - INN concerns** | | | | |
| Similarity with INN | 0 | 0 | 7 | 17 |
| Inclusion of INN stem | 2 | 2 | 2 | 12 |
| **Criterion - Other public health concerns** | | | | |
| Unacceptable qualifiers | 0 | 4 | 6 | 8 |
| Conveys a promotional message | 1 | 1 | 12 | 22 |
| Appears offensive or has a bad connotation | 0 | 0 | 0 | 3 |
| Similarity between name of individual active substance and fixed combinations and/or between fixed combinations | 0 | 0 | 5 | 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 NOVEMBER 2007**

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

| | 1995 - 2006 | 2007 | Overall Total |
|---|---|---|---|
| Scientific Advice | 718 | 148 | 866 |
| Follow-up to Scientific Advice | 127 | 38 | 165 |
| Protocol Assistance | 157 | 39 | 196 |
| Follow-up to Protocol Assistance | 40 | 23 | 63 |
| | **1042** | **248** | **1290** |

## OUTCOME OF THE OCTOBER 2007 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 | Diagnosis of growth hormone deficiency | X | | | | X | X | X | |
| Chemical | Treatment of type 2 diabetes mellitus. | X | | | | | | X | |
| Biological | Treatment of type 2 diabetes | | | X | | | X | X | |
| Chemical | Treatment of acute uncomplicated Diverticulitis | X | | | | | | X | |
| Chemical | Reduction of incidence of symptomatic gastroduodenal ulcer disease | X | | | | | X | X | |
| Chemical | Treatment of newly diagnosed glioblastoma multiforme | | 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 cancer | X | | | | | | X | |
| Biological | Treatment of Neutropenias | | | X | | | | X | |
| Chemical | Treatment of relapsing multiple sclerosis | | | X | | | | X | |
| Chemical | Treatment of locally advanced or metastatic breast cancer | X | | | | | | X | |
| Chemical | Treatment of Onchocerciasis | X | | | | | | X | |
| Chemical | Treatment of thrombocytopenia | X | | | | | | X | |
| Biological | Treatment of thromoboembolic disorder | X | | | | X | X | X | |
| Chemical | Prevention of venous thromboembolic events | X | | | | | | X | |
| Chemical | Treatment of essential hypertension | X | | | | X | | | |
| Chemical | Treatment of hypercholesterol-aemia or mixed hyperlipidemia | | X | | | X | X | X | |
| Chemical | Treatment of HIV-1 infection | | | X | | | X | X | |
| Biological | Immunization against influenza | | | X | | | | X | |
| Biological | Prevention of antibiotic-associated pathogen intestinal colonization | | | X | | | | X | |
| Chemical | Treatment of chronic HCV infection | X | | | | | X | X | |
| Chemical | Treatment of neurogenic detrusor overactivity | 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 | | | | |
| Biological | Treatment of Duchenne muscular dystrophy | X | | | | X | X | X | |
| Chemical | Treatment of Huntington disease | | | | X | | | X | |
| Chemical | Treatment of moderate to severe pain | X | | | | X | | X | |
| Chemical | Treatment of Parkinson's disease | X | | | | | | X | |
| Chemical | Treatment of cancer pain | X | | | | | | X | |
| Chemical | Treatment of mild to moderately severe dementia of the Alzheimer type | X | | | | X | X | X | |
| Chemical | Treatment of cystic fibrosis | | | | X | | X | X | X |
| Chemical | Treatment of asthma | X | | | | | X | | |
| Chemical | Treatment of Idiopathic Pulmonary Fibrosis | | | | X | | X | | |

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 20 Scientific Advice letters, 1 Protocol Assistance letter, 6 Follow-up Scientific Advice and 3 Follow-up Protocol Assistance letters were adopted at the 12-15 November 2007 CHMP meeting.

**New requests for Scientific Advice Procedures**

The Committee accepted 38 new Requests for which the procedure started at the SAWP meeting held on 29-31 October 2007. The new requests are divided as follows: 23 Initial Scientific Advice, 5 Follow-up Scientific Advice, 7 Initial Protocol Assistance and 3 Follow-up Protocol Assistance.

# DOCUMENTS PREPARED BY THE CHMP WORKING PARTIES ADOPTED DURING THE NOVEMBER 2007 CHMP MEETING

## BIOLOGICS WORKING PARTY (BWP)

| Reference number | Document | Status[3] |
|---|---|---|
| EMEA/CHMP/BWP/ 271475/2006<br><br>EMEA/CHMP/BWP/ 329778/2007 | Guidance document for potency testing of cell based immunotherapy medicinal products for the treatment of cancer<br>Overview of comments | Adopted |

## CHMP PHARMACOGENETICS WORKING PARTY (PgWP)

| Reference number | Document | Status[3] |
|---|---|---|
| CHMP/PGxWP/278789/ 2006 | Reflection paper on the use of genomics in cardiovascular clinical intervention trials | Adopted |
| CHMP/PGxWP/201914/ 2006 | Reflection Paper on Pharmacogenomic Samples, testing and data handling | Adopted |

## SAFETY WORKING PARTY (SWP)

| Reference number | Document | Status[3] |
|---|---|---|
| CHMP/SWP/431994/2007 | Question & Answers on the CHMP Guideline on the Limits of Genotoxic Impurities | Adopted |

## EFFICACY WORKING PARTY (EWP)

| Reference number | Document | Status[3] |
|---|---|---|
| CPMP/EWP/281/96 Rev. 1 | Guideline on clinical evaluation of medicinal products used in Weight Control | Adopted |
| EMEA/CHMP/EWP/ 517497/2007 | Addendum on Weight Control in Children | Adopted for 3-month public consultation |
| CPMP/EWP/707/98 Rev. 1<br><br>EMEA/519459/2007 /2007 | Guideline on clinical investigation of medicinal products for Prophylaxis of High Intra- and Post-Operative Venous Thromboembolic Risk<br>Overview of comments | 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").