European Medicines Agency
*Evaluation of Medicines for Human Use*

London, 21st December 2007
EMEA/585637/2007

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

The Committee for Medicinal Products for Human Use (CHMP) held its December plenary meeting from 10-14 December 2007.

## CENTRALISED PROCEDURE

### Initial applications for marketing authorisation

The CHMP adopted one positive opinion by majority on an initial marketing authorisation, and two positive opinions by consensus which related to an application for a generic of a centrally authorised product:

- **Tyverb** (lapatinib), from Glaxo Group Limited, indicated, in combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress ErbB2 (HER2) and who have previously been treated. The CHMP recommended a 'conditional approval' for Tyverb, since there is more information to come about the medicine, in particular about its efficacy. EMEA review began on 25 October 2006 with an active review time of 202 days.

- **Myfenax** and **Mycophenolate mofetil Teva** (mycophenolate mofetil), from TEVA Pharma B.V, indicated in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants. The two medicines are generics of CellCept, which has been authorised in the EU since February 1996. EMEA review began on 20 July 2007 with an active review time of 138 days.

Negative opinion

The CHMP also adopted two negative opinions, one by consensus (Kiacta) and one by majority (Rhucin) recommending the refusal of a marketing authorisation, for the following medicines:

- **Kiacta** (eprodisate disodium), from Neurochem Luco II SARL, intended to be used in the treatment of amyloid A (AA) amyloidosis. Kiacta was designated an orphan medicinal product. EMEA review began on 27 September 2006 with an active review time of 202 days.

- **Rhucin** (recombinant human C1 inhibitor), from Pharming Group N.V., intended for the treatment of acute attacks of angioedema in patients with hereditary angioedema. Rhucin was designated an orphan medicinal product. EMEA review began on 16 August 2006 with an active review time of 176 days.

Separate question-and-answer documents explaining the grounds for the negative opinions for Kiacta and Rhucin are 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.

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

The EMEA has been formally requested by UCB S.A, to re-examine the negative opinion for **Cimzia** (certolizumab pegol) to be used for reducing signs and symptoms and maintaining clinical response in patients with active Crohn's disease), adopted during the CHMP meeting on 12-15 November 2007.

Withdrawal

The EMEA has been formally notified by Guerbet of its decision to withdraw its application for a centralised marketing authorisation for the medicinal product **Sinerem** (superparamagneticiron oxidenanoparticles). Sinerem was expected to be used as a contrast agent for lymph node metastases in pelvic cancers. A separate press release with more information is available. The question-and-answer document will be available following the CHMP January 2008 meeting.

## Post-authorisation procedures

Extensions of indication and other recommendations

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

- **Avastin** (bevacizumab), from Roche Registration Ltd, to extend the indication in the treatment of metastatic colorectal cancer in combination with fluropyrimidine-based chemotherapy. Avastin is currently authorised for first-line treatment of patients with certain types of cancer of the colon or rectum, breast cancer, and non-small cell lung cancer. During the November meeting of the CHMP, a recommendation was adopted to also include combination therapy of kidney cancer.

- **Humira** (adalimumab), from Abbott Laboratories, to include reduction in the rate of progression of joint damage and improvement of physical function in the psoriatic arthritis indication. Humira is currently indicated in rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's disease.

- **Mabthera** (rituximab), from Roche Registration Ltd, to extend the indication to include first-line treatment of follicular non-Hodgkin's lymphoma in combination with chemotherapy. Mabthera is currently authorised for first- and second-line treatment of follicular lymphoma and for treatment of CD20 positive diffuse large B cell non- Hodgkin's lymphoma.

- **Xeloda** (capecitabine), from Roche Registration Ltd, to extend the indication in the treatment of patients with metastatic colorectal cancer. Xeloda is currently approved for the treatment of patients with stage III (Dukes' stage C) colon cancer, as first line monotherapy in metastatic colorectal cancer, advanced gastric cancer, locally advanced or metastatic breast cancer.

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

Withdrawal

The EMEA has been formally notified by Novartis Pharma AG of its decision to withdraw its application to extend the marketing authorisation to include a new indication for the medicinal product **Zometa** (zoledronic acid). The extension of indication was to include prevention of fracture and bone loss in postmenopausal women with early-stage breast cancer treated with aromatase inhibitors A separate press release with more information is available. The question-and-answer document will be available in the very near future.

Safety information

The CHMP has concluded that updated warnings to doctors and patients are needed to increase awareness of cases of suicidal ideation and suicide attempts reported in patients using **Champix** (varenicline), a

medicine indicated for smoking cessation in adults. A separate press release and a question-and-answer document with more information are available on the EMEA website.

## OTHER INFORMATION ON THE CENTRALISED PROCEDURE

### Lists of Questions

The Committee adopted nine Lists of Questions on initial applications (three under the mandatory scope, and six under the optional scope).

### Consultation procedure on an ancillary substance in a medical device

The Committee also adopted a positive opinion on human albumin in the context of its use as ancillary medicinal substance in **Medicult a/s HSA-containing media** from **Medicult a/s**. The applicant/Notified Body for the consultation procedure is **DGM, DS Certificering A/S**. EMEA review began on 21 March 2007 with an active review time of 195 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 November 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 November 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**.

The NRG finalised its discussion of Revision 5 of the guideline on the Acceptability of Invented names for Human medicinal products processed through the Centralised procedure (CHMP/328/98).

## REFERRAL PROCEDURES

### Referral procedure concluded

The CHMP concluded two referral procedures, one by consensus (Belara and Belanca) and one by majority (Belanette and Yasminelle). These two referrals were initiated as there was a disagreement between Member States concerning the marketing authorisation of medicines authorised at national level.

The CHMP recommended the refusal of an extension of indication for **Belara** and **Belanca** (30 micrograms ethinyl estradiol plus 2 mg chlormadinone acetate) from Grünenthal, because the data submitted was considered insufficient to demonstrate efficacy in the applied indication (treatment of women suffering from acne). Belara and Balanca are currently authorised in a number of Member States as oral contraceptives. The referral procedure was carried out under Article 6 (12) of Commission Regulation (EC) No 1084/2003.

The CHMP recommended approval of the proposed packaging concept for **Belanette 0.020 mg**, **3mg film coated tablet** and **Yasminelle 0.020 mg, 3mg film coated tablet**, from Bayer Schering Pharma AG. Belanette and Yasminelle are authorised in a number of Member States as oral contraceptives. The referral procedure was initiated under Article 5 (11) of Commission Regulation (EC) No 1084/2003.

**Referral procedures started**

The CHMP started referral procedures for five medicines containing atorvastatin calcium, namely **Atorvatyrol**, (10, 20, 40, 80 mg) from Sandoz GmbH Austria , **Atorvac** (10, 20, 40, 80 mg) and **Atorvastatin Hexal**,(30, 60 mg) both from Hexal Pharma GmbH Austria, **Atorvis** (10, 20, 40, 80 mg)**,** from Sandoz GmbH Austria and **Atorvapharm** (10, 20, 40, 80 mg**),** from 1A Pharma GmbH Austria, because of concerns that bioequivalence with the reference medicine has not been demonstrated sufficiently. The medicines are intended for the treatment of hypercholesterolaemia and prevention of cardiovascular disease. The referral procedure has been initiated under Article 29 of Directive 2001/83/EC as amended.

**Review procedures under Article 107**

The CHMP has recommended the withdrawal of the marketing authorisations for all lumiracoxib-containing medicines, because of the risk of serious side effects affecting the liver. Lumiracoxib is a non-steroidal anti-inflammatory drug (NSAID) that belongs to the group 'COX-2 inhibitors'. It is used for symptomatic relief in the treatment of osteoarthritis of the hip and knee.
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 24th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised procedures-Human) held on 10-12 December 2007. 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 26-28 November 2007. For further details, please see **Annex 6**.

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

## UPCOMING MEETINGS FOLLOWING THE NOVEMBER 2007 CHMP PLENARY MEETING

- The 40th meeting of the CHMP will be held at the EMEA on 21-24 January 2008.
- The next Name Review Group meeting will be held at the EMEA on 21st January 2008.
- The 25th CMD(h) (Co-ordination Group for Mutual Recognition and Decentralised Procedures) will be held at the EMEA on 21-23 January 2008.

## ORGANISATIONAL MATTERS

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

- The adoption of the draft revision 2 of the EC guideline on Summary of Products Characteristics which is now released for 3-month public consultation.
- The adoption of the revised guideline on the Scientific Aspects and Working definitions for the mandatory scope of the centralised procedure.
- The adoption of Revision 5 of the guideline on the acceptability of Invented Names for Human Medicinal Products processed through the centralised procedure (CHMP/328/98). The guideline had previously been adopted by the NRG on 10th December 2007.
- The adoption of the draft implementation plan / innovative drug development approaches that is based on the final report from the EMEA/CHMP-think tank group on innovative drug development
- Follow-on discussion on the draft revised variations regulation.

- Follow-on discussion on the EC legislative proposals to strengthen and rationalise the EU Pharmacovigilance system.
- Follow-on discussion on the Advanced Therapies Regulation and consequences for the CHMP with invitation to CHMP members to express an interest if they wish to become members of the future Committee on Advanced Therapies.
- Follow on discussion of eligibility requests to the centralised procedure for non-prescription medicinal products.
- Discussion on explanotory Paper on the functioning of the EMEA Secretariat.
- Preliminary discussion on the proposals to establish a CHMP Work Plan defining priorities for 2008-2010.

**PROCEDURAL ANNOUNCEMENT**

- Interactions with Applicants during the course of the review

The EMEA also wishes to remind Applicants that initiating contacts with CHMP members during an ongoing review is unacceptable. Contacts should only be made with the appointed Rapporteur, Co-Rapporteur and EMEA Project Team Leader. Any other sources of contact are deemed to be inappropriate with regard to the assessment process .

- New mailbox for the sending of 'Marketing status Reports'

All marketing status reports either relating to the first marketing, updates or cessation of marketing should be sent by the MAH to the mailbox address (marketingstatus@emea.europa.eu) and should be copied to the PTL for the first marketing and the cessation of marketing.

- First marketing reports should be sent within 30 days of the initial placing on the market of the product within the Community;
- Updated reports should be sent at time of PSUR submission and after renewal, annually in accordance with anniversary of the Commission Decision date;
- Cessation reports should be sent 2-month before the interruption, otherwise as soon as the interruption is considered likely or known.

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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 DECEMBER 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 | 36 | 10 | 0 | 8 | 19 | 8 | 11 | 92 | 667 |
| Positive opinions | 18 | 4 | 0 | 2 | 13 | 8 | 5 | 50 | 429 |
| Negative opinions[1] | 1 | 0 | 0 | 0 | 2 | 2 | 2 | 7 | 19 |
| Withdrawals prior to opinion | 4 | 2 | 0 | 0 | 5 | 0 | 2 | 13 | 116 |
| Marketing authorisation granted by the Commission | 23 | 1 | 0 | 1 | 9 | 6 | 10 | 50 | 415 |

## PRE-AUTHORISATION: SCIENTIFIC SERVICES

| Activity (submissions) | 2007 | 1995 onwards |
|---|---|---|
| Compassionate use applications | 0 | 0 |
| Art. 58 applications | 1 | 4 |
| Consultation for medical devices[2] | 2 | 4 |
| 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 DECEMBER 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) | 1006 | 5202 |
| Type II Variations (positive opinions) | 782 | 3644 |
| Type II Variations (negative opinions) | 2 | 10 |
| Annex II Applications (positive opinions) | 27 | 169 |
| Annual Re-assessment (positive opinions) | 26 | - |
| 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** |
| 4 Extensions of indication | 4 Positive opinions |
| 24 SPC changes | 24 Positive opinions |
| 22 Quality changes | 22 Positive opinions |

| Opinions for Annual Re-Assessment applications | | |
|---|---|---|
| **Name of Medicinal Product (INN) MAH** | **Outcome** | **Comments** |
| **Fabrazyme** (agalsidase beta) Genzyme B.V | Positive Opinion adopted | The exceptional circumstances are lifted. |
| **Atryn** (recombinant antithrombin alfa) LEO Pharma A/S | Positive Opinion adopted | The product remains under exceptional circumstances. |
| **Replagal** (agalsidase alfa) TKT Europe-5S AB | Positive Opinion adopted | The product remains under exceptional circumstances. |
| **Benefix** (nonacog alfa) Wyeth Europe Ltd, | 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** |
| N/A | N/A | N/A |

| **Opinions for 5-Year Renewal applications** | | |
|---|---|---|
| **Name of Medicinal Product (INN)<br>MAH** | **Outcome** | **Comments** |
| **Combivir** (lamivudine/zidovudine)<br>GlaxoSmithKline | Positive Opinion adopted | Unlimited validity |
| **Levitra** (vardenafil)<br>Bayer AG | Positive Opinion adopted | Unlimited validity |
| **Vivanza** (vardenafil)<br>Bayer AG | Positive Opinion adopted | Unlimited validity |
| **Ytracis** (yttrium(Y-90))<br>CIS bio International | Positive Opinion adopted | Unlimited validity |

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

**MEDICINAL PRODUCTS GRANTED A COMMUNITY MARKETING AUTHORISATION UNDER THE CENTRALISED PROCEDURE SINCE THE NOVEMBER 2007 CHMP MONTHLY REPORT**

| | |
|---|---|
| **Invented Name** | Tasigna |
| **INN** | Nilotinib |
| **Marketing Authorisation Holder** | Novartis Europharm Limited |
| **Proposed ATC code** | L01XE08 |
| **Indication** | Tasigna is indicated for the treatment of adults with chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukaemia (CML) with resistance or intolerance to prior therapy including imatinib. Efficacy data in patients with CML in blast crisis are not available. |
| **CHMP Opinion date** | 20.09.2007 |
| **Marketing Authorisation Date** | 19.11.2007 |

| | |
|---|---|
| **Invented Name** | Torisel |
| **INN** | temsirolimus |
| **Marketing Authorisation Holder** | Wyeth Europa Ltd |
| **Proposed ATC code** | Not yet available |
| **Indication** | Torisel is indicated for the first-line treatment of patients with advanced renal cell carcinoma who have at least three of six prognostic risk factors. |
| **CHMP Opinion date** | 20.09.2007 |
| **Marketing Authorisation Date** | 19.11.2007 |

| | |
|---|---|
| **Invented Name** | Vectibix |
| **INN** | panitumumab |
| **Marketing Authorisation Holder** | Amgen Europe B.V. |
| **Proposed ATC code** | L01XC08 |
| **Indication** | Vectibix is indicated as monotherapy for the treatment of patients with EGFR expressing metastatic colorectal carcinoma with non-mutated (wild-type) *KRAS* after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens. |
| **CHMP Opinion date** | 20.09.2007 |
| **Marketing Authorisation Date** | 03.12.2007 |

| | |
|---|---|
| **Invented Name** | Nevanac |
| **INN** | nepafenac |
| **Marketing Authorisation Holder** | Alcon Laboratories (UK) Ltd |
| **Proposed ATC code** | S01BC10 |
| **Indication** | Prevention and treatment of postoperative pain and inflammation associated with cataract surgery. |
| **CHMP Opinion date** | 18.10.2007 |
| **Marketing Authorisation Date** | 11.12.2007 |

| | |
|---|---|
| **Invented Name** | Pioglitazone / metformin hydrochloride Takeda |
| **Common Name** | Pioglitazone / metformin hydrochloride |
| **Marketing Authorisation Holder** | Takeda Global Research and Development Centre (Europe) Ltd |
| **Proposed ATC code** | A10BD05 |
| **Indication** | Pioglitazone / metformin hydrochloride Takeda is indicated in the treatment of type 2 diabetes mellitus patients, particularly overweight patients, who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone. |
| **CHMP Opinion date** | 20.09.2007 |
| **Marketing Authorisation Date** | 11.12.2007 |

| | |
|---|---|
| **Invented Name** | Atripla |
| **Common Name** | Efavirenz / emtricitabine / tenofovir disoproxil fumarate |
| **Marketing Authorisation Holder** | Bristol-Myers Squibb Gilead Sciences And Merck Sharp & Dohme Limited |
| **Proposed ATC code** | J05AR06 |
| **Indication** | Atripla is indicated for treatment of human immunodeficiency virus-1 (HIV-1) infection in adults with virologic suppression to HIV-1 RNA levels of < 50 copies/ml on their current combination antiretroviral therapy for more than three months |
| **CHMP Opinion date** | 18.10.2007 |
| **Marketing Authorisation Date** | 13.12.2007 |

## OVERVIEW OF DESIGNATED ORPHAN MEDICINAL PRODUCTS THAT HAVE BEEN THE SUBJECT OF A CENTRALISED APPLICATION FOR MARKETING AUTHORISATION: UPDATE SINCE THE NOVEMBER 2007 CHMP MEETING

| **Active substance** | **Sponsor/applicant** | **EU Designation Number & Date of Orphan Designation** | **Designated Orphan Indication** |
|---|---|---|---|
| Tetrahydrobiopterin | Sapropterin Merck | Merck KGaA | EU/3/04/199 |
| Recombinant megakaryopoiesis-stimulating protein | Nplate | Amgen Europe B.V. | EU/3/05/283 |
| Suberolylanilide Hydroxamic acid | Vorinostat MSD | Merck Sharp & Dohme Limited | EU/3/04/205 |

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

**INVENTED NAME REVIEW GROUP (NRG)**

| | December 2007 | | 2007 | |
|---|---|---|---|---|
| | Accepted | Rejected | Accepted | Rejected |
| Proposed invented names[1] | 15 | 5 | 163 | 148 |
| Justification for retention of invented name *[2] | 1 | 1 | 26 | 29 |

*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 January 2008 NRG meeting

[2] Two of the justification for retention of a proposed invented name have been postponed to the January 2008 NRG meeting;

| | December 2007 | | 2007 | |
|---|---|---|---|---|
| | Accepted | Rejected | Accepted | Rejected |
| Total number of objections raised | 15 | 23 | 282 | 259 |
| **Criterion - Safety concerns** | | | | |
| Similarity with other Invented name | 12 | 13 | 232 | 185 |
| Conveys misleading therapeutic/pharmaceutical connotations | 0 | 4 | 8 | 5 |
| Misleading with respect to composition | 1 | 0 | 8 | 1 |
| **Criterion - INN concerns** | | | | |
| Similarity with INN | 0 | 0 | 7 | 17 |
| Inclusion of INN stem | 0 | 1 | 2 | 13 |
| **Criterion - Other public health concerns** | | | | |
| Unacceptable qualifiers | 1 | 3 | 7 | 11 |
| Conveys a promotional message | 1 | 2 | 13 | 24 |
| 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.

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

| | 1995 - 2006 | 2007 | Overall Total |
|---|---|---|---|
| Scientific Advice | 718 | 169 | 887 |
| Follow-up to Scientific Advice | 127 | 44 | 171 |
| Protocol Assistance | 157 | 41 | 198 |
| Follow-up to Protocol Assistance | 40 | 27 | 67 |
| | **1042** | **281** | **1323** |

## OUTCOME OF THE NOVEMBER 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 | Treatment of Irritable Bowel Syndrome | X | | | | | | X | |
| Biological | Treatment of plaque psoriasis | | | X | | | | X | |
| Chemical | Treatment of prostate cancer | X | | | | | X | X | |
| Chemical | Treatment of bladder cancer | X | | | | X | X | X | |
| Chemical | Treatment of non-small cell lung cancer | X | | | | | | X | |
| Chemical | Treatment of non-small cell lung cancer | | | X | | | | X | |
| Biological | Treatment of Multiple Myeloma | X | | | | X | X | X | |
| Biological | Treatment of Castleman's Disease | 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 paediatric cancers | X | | | | | X | X | |
| Biological | Treatment of chemotherapy induced neutropenia | | | X | | | | X | |
| Chemical | Treatment of Chronic Myeloid Leukaemia | | | | X | | X | X | X |
| Chemical | Treatment of soft tissue sarcoma | X | | | | | | X | |
| Chemical | Treatment of small cell lung cancer | | X | | | X | X | | |
| Chemical | Treatment of small cell lung cancer | | | | X | | | X | X |
| Biological | Treatment of non-small cell lung cancer | | | X | | | | X | |
| Chemical | Treatment of paediatric cancers | X | | | | X | X | | |
| Chemical | Treatment of melanoma | X | | | | | | X | |
| Biological | Prevention of venous thromboembolic events | | | X | | | X | | |
| Biological | Treatment of blunt trauma | X | | | | | | X | |
| Chemical | Treatment of deep vein thrombosis | X | | | | | | X | |
| Chemical | Prevention of paediatric venous thromboembolism | X | | | | | | X | |
| Chemical | Treatment of systemic sclerosis | | X | | | | X | X | |
| Chemical | Treatment of HIV-1 infection | | | X | | X | X | X | |
| Chemical | Treatment of gonadotrophin-independent precocious puberty in boys with testotoxicosis | 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 female infertility and deficient spermatogenesis in male | X | | | | X | X | X | |
| Chemical | Treatment of Parkinson's disease | X | | | | | X | X | |
| Chemical | Treatment of localised postoperative pain | X | | | | | X | X | |
| Chemical | Treatment of major depressive episodes | X | | | | | | X | |
| Chemical | Treatment of major depressive episodes associated with bipolar disorder | X | | | | | | X | |
| Chemical | Treatment of acute sensorineural hearing loss | | | | X | | | X | X |
| Chemical | Prevention of rejection for corneal implant | | | | X | | X | X | |
| Chemical | Treatment of asthma | X | | | | | X | X | |
| Biological | Diagnosis of cow's milk proteins allergy | X | | | | X | X | X | |

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 21 Scientific Advice letters, 2 Protocol Assistance letters, 6 Follow-up Scientific Advice and 4 Follow-up Protocol Assistance letters were adopted at the 10-13 Dec CHMP meeting.

**New requests for Scientific Advice Procedures**

The Committee accepted 25 new Requests for which the procedure started at the SAWP meeting held on 26 Nov 2007. The new requests are divided as follows: 13 Initial Scientific Advice, 4 Follow-up Scientific Advice, 4 Initial Protocol Assistance and 4 Follow-up Protocol Assistance.

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

## BIOLOGICS WORKING PARTY (BWP)

| Reference number | Document | Status[3] |
|---|---|---|
| EMEA/CHMP/BWP/ 99698/2007 | EMEA Fast Track Procedure for Community Human Influenza Inactivated Vaccines Annual Strain(s) Update according to Art 7 of Regulation (EC) No 1085/2003 | Adopted |
| EMEA/CHMP/BWP/ 452081/2007 | Addendum to the Note for Guidance on Plasma Derived medicinal products (CPMP/BWP/269/05 rev. 3) on the replacement of rabbit pyrogen testing by an alternative test for plasma derived medicinal products | Adopted for 6-month public consultation. |

## WORKING PARTY ON SIMILAR BIOLOGICAL MEDICINAL PRODUCTS (BMWP)

| Reference number | Document | Status[3] |
|---|---|---|
| EMEA/CHMP/BMWP/ 14327/2006 | Guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins | Adopted. |

## SAFETY WORKING PARTY (SWP)

| Reference number | Document | Status[3] |
|---|---|---|
| EMEA/CHMP/SWP/ 194898/2006 | Guideline on Carcinogenicity Evaluation of Medicinal Products for the Treatment of HIV Infection | Adopted. |
| EMEA/CHMP/SWP/ 488105/2007 | Reflection paper on *in vitro* investigation of mitochondrial toxicity of anti-HIV nucleoside reverse transcriptase inhibitors | Adopted for 6-month public consultation. |

## EFFICACY WORKING PARTY (EWP)

| Reference number | Document | Status[3] |
|---|---|---|
| CHMP/EWP/439980/2007 | Recommendation for Revision of the Points to Consider on Missing Data | Adopted for 3-month public consultation. |
| CHMP/EWP/490784/2007 | Questions & Answers on the use of Cocktail studies for investigating in vivo drug interaction potential | Adopted. |

## ALL WORKING PARTIES

| Reference number | Document | Status[3] |
|---|---|---|
| EMEA/573031/2007 | Draft revision 2 of the EC guideline on Summary of Product Characteristics | Adopted for 3-month public consultation. |

[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").

**ICH**

| Reference number | Document | Status |
|---|---|---|
| CHMP/ICH/222007/2006 | Q4B Step 4 - Note for evaluation and recommendation of pharmacopoeial texts for use in the ICH regions | Adopted. |