The European Agency for the Evaluation of Medicinal products
Human Medicines Evaluation Unit

1 February 1999
CPMP/159/1999

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 45th plenary meeting from 26 January to 27 January 1999.

The CPMP welcomed one new member, Dr Jens Ersbøll from Denmark succeeding Dr Ib Bo Lumholtz and one new observer, Dr Magnús Jóhannsson from Iceland.

Centralised Procedures

The Committee adopted:

- Four positive opinions[1] on centralised applications:
  - One positive opinion was adopted by consensus relating to a medicinal product (Part A), a combined bacterial and viral paediatric vaccine indicated for vaccination against invasive disease caused by *Haemophilus influenzae* type b and infection caused by hepatitis B.
  - One positive opinion was adopted by consensus relating to a medicinal product (Part A), a viral paediatric vaccine indicated for active immunisation against rotavirus serotypes 1, 2, 3 and 4.
  - One positive opinion under exceptional circumstances was adopted by consensus relating to a medicinal product containing a new active substance (Part B), an iron chelating agent indicated for the treatment of iron overload in patients with thalassemia major for whom deferoxamine therapy is contra-indicated or who present serious toxicity with deferoxamine therapy.
  - One positive opinion was adopted by consensus relating to a medicinal product (Part B) containing a taxane presented for the new indication of treatment of patients with advanced AIDS-related Kaposi's sarcoma (KS) who have failed prior liposomal anthracycline therapy.
- Six positive opinions (four Part A/two Part B) by consensus for centralised type II variations.
- One positive opinion by consensus following the annual re-assessment for a medicinal product (Part A), indicated for the treatment of multiple sclerosis.

The Committee heard one oral presentation from an applicant concerning an ongoing procedure and one oral presentation concerning a procedure given a positive opinion.

Since the CPMP meeting in December 1998, the Committee noted the withdrawal of one centralised application (Part B), for a new active substance because of failure to demonstrate efficacy.

Rapporteurs and Co-Rapporteurs were assigned for seven applications forthcoming in the centralised procedure within the next four months (four Part A/three Part B).

An overview of centralised applications is given in Annex I.

Since the CPMP meeting in December 1998, the European Commission has granted marketing authorisations for:

- Triacelluvax (combined bacterial vaccine), indicated for the active immunisation of children against diphtheria, tetanus and pertussis;
- Forcaltonin (recombinant salmon calcitonin), indicated for the treatment of Paget's disease and hypercalcaemia in malignancy;

[1] Note for Editors:
Applicants may appeal any CPMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion. In line with the decision of the Management Board at its 30 September 1998 meeting, further information on final opinions will be made available 60 days after adoption of the opinion by the CPMP.

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- Emadine (emedastine), indicated for the symptomatic treatment of seasonal allergic conjunctivitis;
- Temodal (temozolomide), indicated for the treatment of glioblastoma multiforme, showing recurrence or progression after standard therapy.

See Annexes II and III for details.`

Scientific Advice

The Committee:

- Accepted eight new and one follow-up request from companies for scientific advice. Co-ordinators were appointed.
- Adopted four scientific advice letters on biotechnology, preclinical and clinical issues, concerning four new medicinal products, three Part A/one Part B, intended for:
  - the stimulation of growth in children suffering from growth hormone deficiency associated with growth failure or retardation;
  - treatment of patients with active rheumatoid arthritis (two products);
  - treatment of patients with diabetes mellitus.

There was an early discussion on the revision of the scientific advice procedure; it is envisaged that the revised document will be adopted at the February CPMP meeting.

Working Parties, Ad Hoc Working Groups and Organisational Matters

The CPMP heard reports from its Quality, Biotechnology, Safety, Efficacy and Pharmacovigilance Working Parties, the Ad Hoc Working Group on Blood Products and the EMEA Ad Hoc Working Group on Herbal Medicinal Products.

BIOTECHNOLOGY WORKING PARTY

One document was adopted:

- The BWP workplan for 1999/2000 (CPMP/BWP/2833/98)

A workshop on the application to pharmaceuticals of assays for markers of TSE was held on 19-20 January 1999 (see Annex IV).

PHARMACOVIGILANCE WORKING PARTY

The following document was adopted and is forwarded to the European Commission for inclusion in Volume 9 of the Rules Governing Medicinal Products in the European Union:

- Draft Notice to Marketing Authorisation Holders (previously chapter V of Notice to Applicants 1994).

EMEA AD HOC WORKING GROUP ON HERBAL MEDICINAL PRODUCTS

The CPMP welcomed the proposals from the EMEA Ad Hoc Working Group on Herbal Medicinal Products (see Annex V) consisting of:

- documents finalised after consultation with Interested Parties until 1 December 1998
- new documents to be released for 3 months consultation by the EMEA were presented to the CPMP. The CPMP welcomed the progress made.

Mutual Recognition

The CPMP noted the report from the mutual recognition facilitation group (MRFG) 25 January 1999, which is circulated together with this Press Release (Annex VI).

Prof. Rolf Bass
Head of Human Medicines Evaluation Unit

This Press Release and other documents are available on the Internet at the following address: http://www.eudra.org/emea.html

CENTRALISED APPLICATIONS TO THE EMEA

	1995-1998			1999		
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**
Scientific advice	33	45	78	3	1	4
Follow-up to scientific advice	9	4	13	0	0	0

	1995-1998			1999		
	Part A	**Part B**	**Total**[1]	**Part A**	**Part B**	**Total**
Applications submitted since 1 January 1995	62	115	177	0	3	3
Withdrawals	11	19	30	0	1	1
Positive CPMP opinions	35	65	100[2]	2	2	4
Negative CPMP opinions	1	2	3[3]	0	0	0
Marketing authorisations granted by the Commission	28	60	88[4]	2	2	4

	1995-1998			1999		
	Part A	**Part B**	**Total**	**Part A**	**Part B**	**Total**
Variations type I	99	168	267	0	13	13
Positive opinions, variations type II	41	77	118	4	2	6[5]
Negative opinions, variations type II	0	2	2	0	0	0
Extensions	25	6	31	0	0	0

[1] These figures include the 18 former concertation procedures submitted before January 1995 of which 14 have been authorised and 4 withdrawn before end 1996
[2] 100 positive opinions corresponding to 76 substances
[3] 3 negative opinions corresponding to 2 substances
[4] 88 marketing authorisations corresponding to 67 substances
[5] 6 positive opinions on type II variations corresponding to 4 substances.

Medicinal products granted a Community Marketing Authorisation under the Centralised Procedure since the December 1998 Press Release

PRODUCT	**Brand name**	**TRIACELLUVAX**
	INN	combined bacterial vaccine
	Part A/B	A
COMPANY ORIGIN	**Country**	Italy
MARKETING AUTHORISATION HOLDER	**Name**	Chiron S.p.A.
THERAPEUTIC AREA	**ATC code**	J07AJ
	Indication	active immunisation of children against diphtheria, tetanus and pertussis
PRESENTATION	**Pharmaceutical form**	suspension for injection
	Strength	0.5 ml
	Number of presentations	3
EMEA/CPMP	**Validation**	20/06/97
	Date of opinion	23/07/98
	Active time	198 days
	Clock stop	194 days
COMMISSION DECISION	**Opinion receipt date**	8/10/98
	Date of Commission decision	11/01/99

PRODUCT	**Brand name**	**FORCALTONIN**
	INN	recombinant salmon calcitonin
	Part A/B	A
COMPANY ORIGIN	**Country**	UK
MARKETING AUTHORISATION HOLDER	**Name**	Unigene UK Ltd.
THERAPEUTIC AREA	**ATC code**	H05BA01
	Indication	treatment of Paget's disease and hypercalcaemia in malignancy
PRESENTATION	**Pharmaceutical form**	solution
	Strength	50 IU/0.5ml
	Number of presentations	2
EMEA/CPMP	**Validation**	26/09/97
	Date of opinion	17/09/98
	Active time	210 days
	Clock stop	147 days
COMMISSION DECISION	**Opinion receipt date**	20/10/98
	Date of Commission decision	11/01/99

PRODUCT	**Brand name**	**EMADINE**
	INN	emedastine
	Part A/B	B
COMPANY ORIGIN	**Country**	UK
MARKETING AUTHORISATION HOLDER	**Name**	Alcon Laboratories (UK) Ltd.
THERAPEUTIC AREA	**ATC code**	S01GX
	Indication	for the symptomatic treatment of seasonal allergic conjunctivitis
PRESENTATION	**Pharmaceutical form**	solution
	Strength	0.05%
	Number of presentations	2
EMEA/CPMP	**Validation**	19/12/97
	Date of opinion	22/10/98
	Active time	182 days
	Clock stop	127 days
COMMISSION DECISION	**Opinion receipt date**	2/12/98
	Date of Commission decision	27/01/99

PRODUCT	**Brand name**	**TEMODAL**
	INN	temozolomide
	Part A/B	B
COMPANY ORIGIN	**Country**	USA
MARKETING AUTHORISATION HOLDER	**Name**	SP Europe, Belgium
THERAPEUTIC AREA	**ATC code**	L01AX03
	Indication	for the treatment of glioblastoma multiforme, showing recurrence or progression after standard therapy
PRESENTATION	**Pharmaceutical form**	capsule
	Strength	5 mg, 20 mg, 100 mg, 250 mg
	Number of presentations	8
EMEA/CPMP	**Validation**	30/01/98
	Date of opinion	22/10/98
	Active time	203 days
	Clock stop	60 days
COMMISSION DECISION	**Opinion receipt date**	25/11/98
	Date of Commission decision	26/01/99

Abstracts for Products granted a Community Marketing Authorisation under the Centralised Procedure since the December 1998 Press Release

TRIACELLUVAX*

International Nonproprietary Name (INN): **Diphtheria, Tetanus and acellular Pertussis vaccine**

On 11 January 1999, the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product Triacelluvax, which is a vaccine containing Diphtheria, Tetanus and acellular Pertussis antigens. This decision was based on the assessment report and on the favourable opinion adopted by the Committee for Proprietary Medicinal Products (CPMP) on 23 July 1998. The Marketing Authorisation Holder responsible for this medicinal product is Chiron S.p.A., Italy.

The approved indication is for the active immunisation of children from 6 weeks up to 7 years of age against diphtheria, tetanus and pertussis. Detailed conditions for the use of this product are described in the Summary of Product Characteristics (SPC) which can be found in the EPAR.

The active substances of Triacelluvax, diphtheria and tetanus toxoids and three purified acellular pertussis antigens are non-infectious substances, which protect infants from diphtheria, tetanus and pertussis by stimulating an immune response (immunogenic activity) against these diseases. The three pertussis antigens are purified from cultures of a *B. pertussis* strain, genetically altered by recombinant DNA technology, to produce a non-toxic form of the pertussis toxin.

Clinical trials were designed to investigate the immunogenic activity, efficacy and the potential for adverse reactions of the vaccine in infants. Comparative studies showed that in addition to eliciting an acceptable immune response, the local and systemic reactions observed following the administration of Triacelluvax were less than those of the whole-cell pertussis vaccines studied.

The most frequently observed adverse events during vaccination were fever, redness, swelling and tenderness at the injection site. Other general symptoms such as irritability, drowsiness, unusual crying and loss of appetite were also reported.

The CPMP, on the basis of efficacy and safety data submitted, considered that Triacelluvax showed adequate evidence of immunogenic activity and a satisfactory safety profile and therefore recommended that the Marketing Authorisation should be granted.

FORCALTONIN*

International Nonproprietary Name (INN): **Recombinant salmon calcitonin**

On 11 January 1999, the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product Forcaltonin, which contains calcitonin (salmon) produced by recombinant DNA technology. This decision was based on the assessment report and on the favourable opinion adopted by the Committee for Proprietary Medicinal Products (CPMP) on 17 September 1998. The Marketing Authorisation Holder responsible for this medicinal product is Unigene UK Limited.

The approved indications are for the treatment of Paget's disease and hypercalcaemia of malignancy. Detailed conditions for the use of this product are described in the Summary of Product Characteristics (SPC) which can be found in the EPAR.

The active substance of Forcaltonin, calcitonin (salmon), is a calciotropic hormone, which inhibits bone resorption by a direct action on osteoclasts. The active substance of Forcaltonin is produced by recombinant DNA technology.

* This text is the Abstract of the complete EPAR

Clinical trials were designed to investigate the pharmacokinetic and pharmacodynamic properties of Forcaltonin in healthy volunteers, and the pharmacodynamic properties in osteoporosis patients. A secondary objective was to monitor safety and tolerability. These studies showed that Forcaltonin was effective and safe in the treatment of patients affected by Paget's disease and hypercalcaemia of malignancy.

The most common adverse reactions observed during treatment were transient and included nausea followed by facial or ear flushing, and vomiting. Less frequent side effects were diarrhoea, headache, and polyuria. The spectrum of side effects that occurred in these studies was not different from the side effects known for salmon calcitonin from published studies.

The CPMP, on the basis of the overall benefit/risk ratio considered that Forcaltonin showed a satisfactory safety profile and adequate evidence of efficacy and tolerability and therefore recommended that the Marketing Authorisation should be granted.

EMADINE*

International Nonproprietary Name (INN): **Emedastine**

On 27 January 1999 the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product Emadine, which contains emedastine difumarate. This decision was based on the assessment report and on the favourable opinion adopted by the Committee for Proprietary Medicinal Products (CPMP) on 22 October 1998. The Marketing Authorisation Holder responsible for this medicinal product is Alcon Laboratories (UK) Ltd., United Kingdom.

The approved indication is for the symptomatic treatment of seasonal allergic conjunctivitis at a dosage of one drop to be applied to the affected eye(s) twice daily. Detailed conditions for the use of this product are described in the Summary of Product Characteristics (SPC) which can be found in the EPAR.

The active substance in this product is emedastine as the difumarate salt. Emedastine has antihistamine properties and is presented at a concentration of 0.05% w/v in a sterile, buffered and preserved solution in a plastic bottle suitable for ophthalmic use.

Over 500 subjects/patients were randomised to be included in efficacy studies involving various concentrations of emedastine, and over 320 of these (ITT) were exposed to emedastine 0.05%, the concentration intended for marketing. The safety database consisted of over 950 subjects/patients exposed to various concentrations of emedastine and over 670 of these were exposed to emedastine 0.05%.

Proof of satisfactory efficacy rests mainly on the results of a comparative clinical trial against a similar product marketed in the EU containing levocabastine 0.05%, with supporting evidence provided by conjunctival allergen challenge (CAC) studies. The results of the clinical trial relating to the relief of redness and itching led the CPMP to conclude that there is enough proof that emedastine is not inferior to levocabastine which can be considered to be a suitable comparator. In the CAC studies, a statistically superior efficacy to placebo was demonstrated with emedastine 0.05% solution in controlling redness and itching in subjects with a history of allergic conjunctivitis. The onset of action occurred in less than 10 minutes and the minimally effective concentration was found to be 0.05%.

Adverse events reported were mild to moderate and usually resolved without treatment. The most frequent ocular events associated with Emadine included ocular discomfort, ocular pruritus, ocular hyperaemia, ocular dryness, blurred vision and corneal staining. No serious adverse events were reported in the studies; no subject aged 3-16 years of age was discontinued due to an adverse event; and no deaths were recorded in the studies.

The CPMP, on the basis of efficacy and safety data submitted, considered that Emadine showed adequate evidence of efficacy and a satisfactory safety profile and therefore recommended that the Marketing Authorisation should be granted.

* This text is the Abstract of the complete EPAR

TEMODAL*

International Nonproprietary Name (INN): **Temozolomide**

Abstract

On 26 January 1999, the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product Temodal, which contains temozolomide. This Decision was based on the assessment report and on the favourable Opinion adopted by the Committee for Proprietary Medicinal Products (CPMP) on 22 October 1998. The Marketing Authorisation Holder responsible for the medicinal product is SP Europe, Belgium.

Temodal capsules are indicated for the treatment of adult patients and children with a specific form of brain tumour (glioblastoma multiforme showing recurrence or progression after standard therapy). Detailed conditions for the use of this product are described in the Summary of Product Characteristics (SPC), which can be found in the EPAR.

Temozolomide is an antitumour agent. It is converted to the active compound monomethyl triazenoimidazole carboxamide (MTIC). MTIC is a cytotoxic agent. Data on clinical efficacy in patients were based on two clinical trials. One was a non-comparative trial in 138 patients and the other was a randomised reference controlled trial of temozolomide and procarbazine in a total of 225 patients. In both trials, the primary endpoint was progression-free survival (PFS). In the randomised trial, the 6 month PFS was significantly greater for temozolomide than for procarbazine (21% vs 8%). A small benefit of temozolomide with regard to providing relief compared to procarbazine was shown.

Temodal treatment can cause thrombocytopenia and neutropenia. This may cause increased bruising or bleeding, anaemia, fever and/or a reduced resistance to infections. Other undesirable effects include nausea (feeling sick), vomiting, tiredness, constipation, headache, loss of appetite or weight, diarrhoea, sleepiness, fever, rash, weakness, pain, dizziness, shortness of breath, and hair loss.

The CPMP, on the basis of the overall benefit/risk ratio considered that Temodal showed a satisfactory safety profile and adequate evidence of efficacy and therefore recommended that the Marketing Authorisation should be granted.

* This text is the Abstract of the complete EPAR

EMEA Workshop on the application to pharmaceuticals of assays for markers of Transmissible Spongiform Encephalopathies (TSE)

19-20 January 1999.

In early 1998, the CPMP released a position statement on new variant Creutzfeldt-Jakob disease (nvCJD), CPMP/201/98. This statement included comment on the desirability of developing assays for markers of transmissible spongiform encephalopathies. A follow up meeting was held at the EMEA to share information on the current status of these assays and their possible use as diagnostic or screening tools and in evaluating manufacturing processes for pharmaceuticals. The preliminary conclusions drawn from the meeting are:

- There has been substantial progress in the development of assays for markers of transmissible spongiform encephalopathies
- Companies are developing *in vitro* assays (such as Western blot, ELISA, DELFIA) to detect the pathological prion protein. However, at present the predictive value of these assays has not been established, although in experimental models there is some correlation with TSE infectivity. Bioassays are the only way to directly measure infectivity.
- Focus is now being made on a number of technical issues (such as sensitivity, robustness, through-put/automation) which need to be resolved before these techniques can be applied on a routine basis to the monitoring of starting materials (animal/human) used in the manufacture of pharmaceuticals. In addition, the applicability of these *in-vitro* assays to tissues other than neuronal is being investigated. It is likely that one of the first applications of these tests may be as a tool in the evaluation of pharmaceutical manufacturing processes for their capacity to remove/inactivate transmissible agents, and some preliminary work in this area is already on-going.
- There is a need for a panel of international reference materials. It was stressed that collaborative studies were required to be able to optimise, validate and compare the various immuno-assays under development. These matters will require the involvement of the European Pharmacopoeia.
- The CPMP position statement on CJD and nvCJD issued in February 1998 remains valid. This position statement (CPMP/201/98) is available on the EMEA web site.

Draft proposals from the Ad Hoc Working Group on Herbal Medicinal Products released for 3 months consultation by the EMEA

- Draft Comments on the Commission Regulation (EC) No. 541/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation granted by a competent authority of a Member State as amended by Commission Regulation (EC) No. 1146/98 - (EMEA/HMPWG/20/99)

- Draft Comments on the European Commission Guideline on dossier requirements for Type I variations - Notice to Applicants Vol. 2A (EMEA/HMPWG/22/99)

- Draft Comments on the draft Directive on Good Manufacturing Practice (GMP) guide for starting materials of medicinal products and inspection of manufacturers - (EMEA/HMPWG/17/99)

- Draft Comments on the document Good Agricultural Practice (GAP) from the European Herbs Growers and Producers Association (Europam) of 5 August 1998 - (EMEA/HMPWG/18/99)

- Draft Note for guidance on specifications: test procedures and acceptance criteria for herbal drug preparations (herbal drugs) and herbal medicinal products - (EMEA/HMPWG/19/99)

- Draft Comments on the CPMP Note for guidance on stability testing after a Type II variation to a marketing authorisation - (EMEA/HMPWG/21/99)

- Draft Points to consider on the evidence of safety and efficacy required for well-established herbal medicinal products in bibliographic applications - (EMEA/HMPWG/23/99)

- Draft Proposal for a core-SPC for *Ispaghula husk* - (EMEA/HMPWG/24/99)

Final proposals from the Ad Hoc Working Group on Herbal Medicinal Products (revised after 3 months consultation)

- Final Comments for revision of Notice to Applicants Volume 2B Part IC1 "Tabular formats specific to herbal medicinal products" - (EMEA/HMPWG/16/99)

- Final Comments for revision of Notice to Applicants Volume 2B Part II: Concerning chemical, pharmaceutical and biological documentation for vegetable medicinal products - (EMEA/HMPWG/8/99)

- Final Note for guidance on fixed combinations of herbal medicinal products with long-term marketing experience - guidance to facilitate mutual recognition and use of bibliographic data - (EMEA/HMPWG/15/99)

MRFG
Mutual Recognition Facilitation Group

Report from the meeting held on 25 January 1999

The MRFG noted that 13 new mutual recognition procedures were finalised during the month of December 1998, as well as 41 type I and 24 type II variations.

The status as of 31 December and for the whole year 1998 of procedures under mutual recognition is as follows:

Year	Procedures from New applications finalised	Procedures from New applications in process	Procedures from Type I variations finalised	Procedures from Type I variations pending	Procedures from Type II variations finalised	Procedures from Type II variations pending	Arbitrations referred to CPMP
1998	182	24	339	39	222	113	1 N.A. 4 var.

The status of the 4 years since the Mutual Recognition Procedure started is as follows (further detailed statistics can be found at the MRFG Website):

Years	Procedures from New applications finalised	Procedures from Type I variations finalised	Procedures from Type II variations finalised	Arbitrations referred to CPMP
1995-1998	422	505	475	4 New Applications + 6 Variations

In 1998 the categories of the finalised procedures are as follows:

New active substance[1]	Line extensions [2]	Fixed comb.	Generics	Herbal products[3]	OTC[4]	Others[5]
37	25	25	45	1	7	42

9 new procedures (regarding 11 products) started in December 1998. The categories of these procedures are as follows:

New active substance[1]	Line extensions [2]	Fixed comb.	Generics	Herbal products[3]	OTC[4]	Blood products	Vaccines	Others[5]
1	1	0	6	0	0	1	0	0

1. When in one of the involved Member States it concerns a new active substance according to the definition in the Notice to Applicants Part IIA;
2. Line extensions are those applications which extend a range of products, e.g. an additional strength, or a new pharmaceutical form from the same Marketing Authorisation Holder;
3. In this category products are classified as herbals when the RMS has considered them as herbal product;
4. In this category products are classified as OTC products when the RMS has approved it for OTC use, although the legal status is not part of the Mutual Recognition Procedure;
5. When the product is not classified in the previous six categories.

Each application can be classified in only one category.

Number of countries involved in the new applications procedures started in December 1998:

Reference Member State (number of products involved in the procedure)	Number of CMSs involved in the procedure
DE (1)	1
FI (1)	5
NL (2)	5
NL (1)	1
NL (2)	6
UK (1)	7
UK (1)	1
UK (1)	13
UK (1)	1

General issues

- Further updated statistics relating to the years 1995 to 1998 are published in the MRFG Website.
- The group wants to draw attention to the fact that requests for break-out sessions can only be asked by the Reference Member State (RMS) and not by companies. Companies are advised to liaise with the RMS on this matter.
- The SOP for break-out-session ("Mutual Recognition Facilitation Group Break-out Session Protocol" dated 22.06.98) was adopted as final. The sentence that it will be reviewed after six months is now deleted.
- The Commission stated that a Marketing Authorisation (MA) given in the RMS can only be recognised once by the Concerned Member States (CMSs), as only one MA is concerned.

All documents mentioned in this press release can be found at the MRFG Website at the European Medicines Authorities Windows under the heading SOP.

Information on the above mentioned issues can be obtained by the presiding chair of the MRFG:

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http://heads.medagencies.org/