The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit 30 January 1998
CPMP/069/98

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 34th plenary meeting on 27-28 January 1998.
At the beginning of this new term, Prof. J.M. Alexandre was re-elected chairperson and Dr. M. Teeling was elected vice-chairperson for the period of 1998 - 2000. Five new CPMP members were introduced: Dr. I.B. Lumholtz from Denmark replacing Pharm. H. Hovgaard, Dr. M. Haase from Germany replacing Prof. R. Kurth, Pharm. M. Avgerinos from Greece replacing Prof. M. Marselos, Prof. R. Gaspar from Portugal replacing Prof. J. Guimaraes Morais and Prof. B. Odlind from Sweden replacing Prof. K. Strandberg.
The updated list of CPMP members is annexed to this press release (Annex IV).

Centralised Procedures
The Committee adopted by consensus/majority the following opinions:

- Three positive opinions on centralised applications
  - One relating to a product containing a new active substance (Part B) which is indicated as a diagnostic transpulmonary echocardiographic contrast agent (consensus).
  - One relating to a product containing a new active substance (Part B) indicated for the treatment of mild to moderately severe Alzheimer's dementia (majority of votes).
  - One relating to a biotechnological product (Part A) indicated for the treatment of patients with relapsed or chemoresistant follicular non-Hodgkin's lymphoma (consensus).
- Two positive opinions were adopted for centralised type II variations (consensus).

Rapporteurs and co-rapporteurs were assigned for eleven applications forthcoming in the centralised procedure within the next four months; 1 Part A and 10 Part B, including one double application for the same active substance.

Since the CPMP meeting in December 1997, the European Commission has granted a marketing authorisation for VIRACEPT (nelfinavir) for the treatment of HIV (Annex II/III).

An overview of centralised applications is given in Annex I and II.

Working Parties, Ad Hoc Expert Groups and Organisational Matters
The CPMP heard reports from its Quality, Biotechnology, Safety, Efficacy and Pharmacovigilance Working Parties (especially in preparation of the upcoming ICH-steering Committee/Working Group meetings); and from the Ad Hoc Expert Working Group on Update of Guidance on SPCs.

Quality Working Party:
The following documents were adopted:
- Quality Working Party Workplan 1998/1999 (CPMP/QWP/117/98)
- Note for Guidance on summary of requirements for active substances in Part II of the dossier (CPMP/QWP/297/97)
- Note for Guidance on declaration of storage conditions for medicinal products in the products particulars (CPMP/QWP/609/96)
- Note for Guidance on maximum shelf-life for sterile products for human use after first opening or following re-constitution (CPMP/QWP/159/96)
- Note for Guidance on development pharmaceutics (CPMP/QWP/155/96)

The following document was released for six months consultation:
- Decision trees for the selection of sterilisation methods (CPMP/QWP/054/98)

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This is an annex to the Note for Guidance on development pharmaceutics (CPMP/QWP/155/96).

Efficacy Working Party

The following documents were released for three months consultation:

- Points to consider on clinical investigation of medicinal products used in the treatment of osteoarthritis (CPMP/EWP/784/97)
- Points to consider on clinical investigation of slow-acting anti rheumatic medicinal products in rheumatoid arthritis (CPMP/EWP/556/95)

Safety Working Party

The following document was released for 6 months consultation:

- Safety Studies for Gene Therapy Products (CPMP/SWP/112/98)
  This is an annex to the Note for Guidance on Gene therapy product quality aspects in the production of vectors and genetically modified somatic cells published in Volume III of the Rules Governing Medicinal Products in the European Union, January 1996 (III/5380/96).

Pharmacovigilance Working Party

The following document was adopted:

- Principles of providing the World Health Organisation with pharmacovigilance information (CPMP/PhVWP/053/98)

Ad Hoc Working Group on Herbal Medicinal Products

At the request of the European Commission, the EMEA Executive Director asked for the support of the EMEA Management Board to set up in May 1997, an Ad Hoc Working Group on Herbal Medicinal Products.

On the basis of the reports from the group, the interim results of three meetings at the EMEA were presented by the Chairperson, Dr. Konstantin Keller (Executive Summary, EMEA/adhocHMPWG/1120/97 Rev.1). Proposals for solving the difficulties, which were previously encountered in the assessment and authorisation of Herbal Medicinal Products are gathered in a document released by the EMEA for 3 months consultation (EMEA/adhocHMPWG/114/98), which was noted by the Committee.

Mutual Recognition

The CPMP noted the report from the Mutual Recognition Facilitation Group (MRFG) (26 January 1998) which is circulated together with this press release.

Prof. R. 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

	Centralised Applications		Total*
	Part A	Part B	
Applications submitted since 1 January 1995	**47**	**89**	**136**
Withdrawn	**3**	**8**	**11**
Opinions given by the CPMP	**26**	**39**	**65** **
Marketing Authorisations granted by the Commission	**23**	**28**	**51** ***

* These figures include the 18 ex-concertation procedures submitted before January 1995 of which 14 have been authorised and 4 withdrawn before end 1996

** 65 Opinions corresponding to 53 substances

*** 51 Marketing Authorisations corresponding to 43 substances

	Final		Total
	Part A	Part B	A + B
Variations type I	**64**	**69**	**133**
Variations type II	**18**	**35**	**53**
Extensions	**10**	**2**	**12**
Scientific advice	**46**		**46**

Medicinal Products granted a Community Marketing Authorisation under the Centralised Procedure

Product a) Brandname b) INN c) Part A/B	**Company** a) Name b) Origin	**Therapeutic Area** a) ATC b) Indication	**Presentation** a) Form b) Dose c) Number of Presentations	**EMEA/CPMP** a) Validation b) Opinion c) Active Time d) Clock stop	**Commission** a) Opinion received on b) Date of decision c) Date of notification d) OJ No.
a) **Viracept** b) Nelfinavir c) Part B	a) Roche Registra-tion Ltd. b) CH	a) J05 AX0 b) Antiviral agent	a) Tablet, Oral powder b) 250 mg, 50 mg/g c) 3 Presentations	a) 18.02.97 b) 24.09.97 c) 180 Days d) 34 Days	a) 31.10.97 b) 22.01.98 c) d)

VIRACEPT

International Non-proprietary Name (INN): **Nelfinavir**

Abstract

On 22 January 1998, the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product Viracept, which contains nelfinavir. This decision was based on the favourable opinion and on the assessment report adopted by the Committee for Proprietary Medicinal Products (CPMP) on 24 September 1997. The Marketing Authorisation Holder responsible for this medicinal product is Roche Registration Limited.

The approved indication is for use in combination with antiretroviral nucleoside analogues for the treatment of Human Immunodeficiency Virus (HIV-1) patients, aged 2 years and older, with advanced or progressive immunodeficiency. Detailed conditions for the use of this product are described in the Summary of Product Characteristics (SPC) which can be found in this EPAR and is available in all European Union official languages.

The active substance of Viracept, nelfinavir, is an antiretroviral agent which inhibits the action of HIV protease, an enzyme involved in the final development of HIV. Nelfinavir prevents, therefore, the production of new infectious viral particles.

Clinical trials were designed to investigate the activity of nelfinavir when administered alone or in combination. Two studies examined nelfinavir in combination regimens, one in combination with stavudine compared to stavudine alone in patients naive to stavudine and protease inhibitors, and a second in combination with zidovudine and lamivudine compared to zidovudine and lamivudine alone in patients naive to all anti-retroviral treatment. These studies demonstrated efficacy in adults based on additional reductions in plasma viral load and, to a lesser extent, on increases in CD_4 counts which resulted from addition of nelfinavir to the regimens of one or two antiretroviral nucleoside analogues. Clinical studies are underway to evaluate the clinical benefits of combination regimens.

The most common adverse events observed during nelfinavir treatment were diarrhoea, asthenia and headache. Almost all events were of mild or moderate severity.

Limited data on the safety and pharmacokinetics related to the administration of nelfinavir to children up to the age of 13 were submitted. These data allowed for identification of an appropriate dose in children. There is no suggestion at present that the safety profile in children will differ significantly from that in adults.

The CPMP, on the basis of efficacy and safety data submitted, recommended that the Marketing Authorisation should be granted "under exceptional circumstances". The Marketing Authorisation Holder will submit additional information regarding the pharmaceutical, toxicological and clinical data. All additional studies will be carefully monitored and the results will be reviewed by the CPMP.

This text is also published as Abstract of the EPAR for Viracept

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Report from the meeting held on 26 th January 1998

The MRFG noted that 10 new mutual recognition procedures have been finalised by the end of 1997 as well as 2 type I and 11 type II variations.
The status as of 31st December 1997 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
1997	146	39	101	22	163	73	1 N.A. + 1 Var.

Between 15th December 1997 and 31 st December 1997 no new procedures have been started.

The status of the 3 years since the Mutual Recognition Procedures have been started is as follows:

Years	Procedures from New applications finalised	Procedures from Type I variations finalised	Procedures from Type II variations finalised	Arbitrations referred to CPMP
1995-1997	240	166	253	3 New Applications + 2 Variations

General issues

- The Group welcomed representatives from the Icelandic and Norwegian competent authorities who were attending as observers for the first time.
- The Group considered a report from the EudraTrack sub-group. There continue to be operational problems with EudraTrack and as a result the pilot phase has had to be extended for a further 3 months.
- The Group discussed a number of procedural issues with representatives of the European Commission.
- The Group met with representatives of the European Vaccine Manufacturers to review and discuss the on-going procedure for handling core dossiers for influenza vaccines through the Mutual Recognition Procedure and the subsequent annual updates for the new season 1998/99 onwards. Both parties were pleased with the progress being achieved.

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

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