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

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CPMP/644/96

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 18th plenary meeting on 16-17 July 1996.

Centralised Procedures

The Committee adopted by consensus 2 positive opinions (Part B) for the same new active substance for the treatment of ovarian metastatic carcinoma, to be forwarded to the European Commission.

In total 28 positive opinions have now been adopted by consensus by the CPMP since May 1995 (15 new centralised and 13 ex-concertation procedures).

The Committee also adopted by consensus a positive opinion for the third type II variation procedure concerning a recent European Marketing Authorisation. Furthermore, a positive opinion was adopted concerning an extension of an European Marketing Authorisation for an additional strength.

The Committee noted that 13 community marketing authorisations have now been granted by the European Commission, following the recent adoption of authorisations for Caelyx (doxorubicin HCL), Bondronat (ibandronic acid) and Bonviva (ibandronic acid) (for further details see annexe 1). The new European Public Assessment Reports (EPAR) will be made available.

Ten new applications have been assigned to Rapporteurs and Co-Rapporteurs under the Centralised Procedure (5 Part A and 5 Part B).

The Committee agreed and adopted a description of:

> *"Accelerated Evaluation of Products Indicated for Serious Diseases (Life Threatening or Heavy Disabling Diseases) (CPMP/495/96)"*,

thereby creating a transparent mechanism. The Committee stresses that accelerated evaluation would be initiated and completed in exceptional cases only.

To avoid problems during the review of centralised applications, the Committee reminds companies to send copies of their application within 10 days of the validation of the dossier to the CPMP Members designated by the Secretariat.

Pharmacovigilance

The information concerning three new AIDS treatments (protease inhibitors) has been reviewed in relation to recent case reports of spontaneous bleeding in haemophilic patients (see Annex 2).

The Committee adopted by consensus a series of revised opinions following an appeal procedure on the previous opinions for anorectic agents given in February 1996.

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Scientific Advice

The CPMP adopted two reports on scientific advice and one follow up of a previously given advice by consensus, bringing the total to 12 since the procedure was introduced in 1995. A break-out session was held with another company.

Mutual Recognition

The Committee adopted the EMEA-Standard Operating Procedure on

> *"Arbitration under the Decentralised Procedure for Marketing Authorisation" (Article 10 of Council Directive 75/319/EEC EMEA/SOP/001/96).*

The current status as at 16 July 1996 of procedures under the mutual recognition procedure was as follows:

New applications finalised	New applications pending	Type I variations finalised	Type I variations pending	Type II variations finalised	Type II variations pending	Arbitrations referred to CPMP
40	22	39	6	49	37	3*

* two for full applications, one for variations

Multistate Procedures

The Committee unanimously adopted a (non-binding) positive opinion from a multistate procedure which had been initiated before 1995, to be forwarded to the concerned Member States' competent authorities for the granting of national marketing authorisations.

Working Parties/ICH

Working Parties
The CPMP heard reports from its Quality, Biotechnology, Safety and Pharmacovigilance Working Parties.

One Quality guideline: "Guideline for Inclusion of Antioxidants and Antimicrobial Preservatives in Medicinal Products" (CPMP/CVMP/QWP/115/95), and one Biotechnology guideline: "Note for Guidance on Harmonisation of Requirements for Influenza Vaccines (CPMP/BWP/214/96)" were released for consultation until January 1997.

ICH
One ICH topic step 4 was adopted by the Committee and will be implemented in January 1997: E6; "Good Clinical Practice; Consolidated Guideline" (CPMP/ICH/135/95).

Prof. Rolf Bass
Head of Human Medicines Unit

This press release and other documents are available on the Internet (http://www.eudra.org/emea.html)

Annexe: 1. Medicinal Products with a Marketing Authorisation for the EU under the Centralised Procedure
Annexe: 2. Information concerning protease inhibitors treatment (indinavir, ritonavir, saquinavir) of haemophilic patients type A and B
Annexe: 3. List of Documents/Guidelines

Annexe 1

Product a) Brandname b) INN c) List 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) Date of decision b) OJ No.
a) **Gonal-F** b) Follitropin-alpha c) List A	a) Serono Laboratories b) IT/CH	a) L02A X b) Treatment of infertility	a) Powder for injection b) 75 IU, 150 IU c) 16 Presentations	a) 01.01.95 b) 17.05.95 c) 107 days d) 30 days	a) 23.10.95 b) OJ No.C 22 of 26.01.96
a) **Betaferon** b) Interferon beta - 1b c) List A	a) Schering AG b) DE	a) LO3A A.... b) Immuno-stimulation, multiple sclerosis	a) Powder for injection b) 0.25 mg/ml c) 1 Presentation	a) 01.01.95 b) 12.07.95 c) 138 days d) 55 days	a) 30.11.95 b) OJ No.C 22 of 26.01.96
a) **Taxotere** b) Docetaxel c) List B	a) Rhone-Poulenc Rorer b) FR	a) LO1X..... b) cytostatic	a) Concentrate for infusion b) 80 mg/2 ml 20 mg/0.5 ml c) 2 Presentations	a) 01.01.95 b) 12.07.95 c) 100 days d) 93 days	a) 27.11.95 b) OJ No.C 22 of 26.01.96
a) **NovoSeven** b) Factor VIIa c) List A	a) Novo-Nordisk b) DK	a) B02B D05 b) Coagulation factor	a) Powder for injection b) 240 KIU c) Presentations	a) 01.01.95 b) 12.09.95 c) 210 days d) 80 days	a) 23.02.96 b) OJ No. C 93 of 29.03.96
a) **CellCept** b) Mycophenolate Mofetil c) List B	a) Hoffmann-La Roche b) CH	a) LO4AX b) Prevention of kidney trans-plant rejection	a) Capsules, Tablets b) 250 mg, 500 mg c) 2 Presentations	a) 01.01.95 b) 17.10.95 c) 243 days d) 47 days	a) 14.02.96 b) OJ No. C 54 of 23.02.96

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a) **Fareston** b) Toremifene c) List B	a) Orion b) FIN	a) LO2BA02 b) Treatment of certain breast tumors	a) Tablets b) 60 mg c) 2 Presentations	a) 01.01.95 b) 17.10.95 c) 240 days d) 50 days	a) 14.02.96 b) OJ No. C 54 of 23.02.96
a) **Humalog** b) Insulin Lispro c) List A	a) Lilly Industries b) USA	a) b) Diabetes mellitus	a) Solution for injection b) 40 IU/ml vials 100 IU/ml vials + Cartridges c) 3 Presentations	a) 01.01.95 b) 22.11.95 c) 250 Days d) 86 Days	a) 30.04.96 b) OJ No. C 156 of 31.05.96
a) **Puregon** b) Follitropin-beta c) List A	a) Organon b) NL	a) GO3GA b) Infertility treatment	a) Powder for injection b) 50 IU 100 IU 75 IU 150 IU c) 16 Presentations	a) 01.01.95 b) 20.12.95 c) 203 Days d) 151 Days	a) 03.05.96 b) OJ No. C 156 of 31.05.96
a) **Zerit** b) Stavudine c) List B	a) Bristol Myers Squibb b) UK	a) JO5AX04 b) Second line mono-therapy of HIV infection	a) Powder for oral solution, capsules b) 1 mg/ml, 15 mg/ml 20 mg/ml, 30 mg/ml 40 mg/ml c) 9 Presentations	a) 14.08.95 b) 16.01.96 c) 150 Days d) ----------	a) 08.05.96 b) OJ No. C 156 of 31.05.96
a) **Rilutek** b) Riluzole c) List B	a) Rhone-Poulenc Rorer b) FR	a) NO7X b) Amyo-trophic lateral sclerosis	a) Tablets b) 50 mg c) 1 Presentation	a) 19.07.95 b) 13.02.96 c) 161 Days d) 41 Days	a) 10.06.96 b) OJ No. C 188 of 28.06.96
a) **Caelyx** b) Doxorubicin-HCl c) List B	a) Sequus Pharmaceutical Inc b) UK	a) LO1DB b) AIDS-related Kaposi's Sarcoma	a) Concentrate for infusion b) 20 mg in 10 ml/vial c) 1 Presentation	a) 01.01.95 b) 13.02.96 c) 222 Days d) 150 Days	a) 21.06.96 b)

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a) **Bondronat** b) Ibandronic acid c) List B	a) Boehringer Mannheim b) DE	a) MO5BA b) Hyper-calcemia of malignancy	a) Concentrate for infusion b) 1mg in 1ml/ ampulle c) 1 Presentation	a) 01.06.95 b) 13.02.96 c) 203 Days d) 52 Days	a) 25.06.96 b)
a) **Bonviva** b) Ibandronic acid c) List B	a) Galenus Mannheim b) DE	a) MO5BA b) Hyper-calcemia of malignancy	a) Concentrate for infusion b) 1mg in 1ml/ ampulle c) 1 Presentation	a) 01.06.95 b) 13.02.96 c) 203 Days d) 52 Days	a) 25.06.96 b)

Annexe 2

Information concerning protease inhibitors treatment (indinavir, ritonavir, saquinavir) of haemophilic patients type A and B

In France, where these products are currently prescribed under a Temporary Authorisation for Use (ATU), there have been several reports of increased bleeding, including spontaneous skin haematomas and haemarthroses, in haemophiliac patients type A and B treated with these protease inhibitors. In some patients an increased dose of factor VIII was required. In some of the reported cases it has been possible to continue treatment with protease inhibitors. A causal relationship has not been definitely established, but haemophiliac patients should be made aware of the possibility of increased bleeding.

As these products are currently available in many member states on a compassionate use basis, prescribers should be aware of this information.

Haemophiliac patients treated with these products should be advised that some haemophiliac patients have experienced increased bleeding while taking this treatment, and should this occur immediate medical advice should be sought.

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Annexe 3

List of Documents/Guidelines made available:

- Guideline for Inclusion Of Antioxidants And Antimicrobial Preservatives In Medicinal Products (CPMP/CVMP/QWP/115/95) released for consultation until 17 January 1997.
- Guideline on Good Clinical Practice (consolidated guideline) (CPMP/ICH/135/95). Adopted for coming into force 17 January 1997.
- EMEA Standard Operating Procedure (SOP) on: "Arbitration under the Decentralised Procedure for Marketing Authorisation" (Article 10, CD 75/319/EEC EMEA/SOP/001/96).
- CPMP Agreement on "Accelerated Evaluation of Products Indicated for Serious Diseases (Life Threatening or Heavy Disabling Diseases)" (CPMP/495/96),
- Note for Guidance on Harmonisation of Requirements for Influenza Vaccines (CPMP/BWP/214/96)