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

CPMP/182/97
20-02-97

**PRESS RELEASE**

The Committee for Proprietary Medicinal Products (CPMP) held its 24th plenary meeting on 18-19 February 1997 at the EMEA headquarters in London.

Centralised Procedures

The Committee adopted by consensus three positive Opinions for three medicinal products; one product for the treatment of diabetes mellitus (Part A abridged application for a product which has already been approved); one product containing a new active substance (Part B) for the treatment of nephropathic cystinosis and the third one a new diagnostic contrast medium for the detection of liver lesions (Part B). The Opinions will be forwarded to the European Commission.

The Committee also adopted by consensus two positive Opinions for centralised Type II Variations and three positive Opinions for centralised Type I Variations following the Type II procedure.

Since the last CPMP meeting, the European Commission has granted a marketing authorisation for the vaccine Twinrix Paediatrics (combined hepatitis A and B). The corresponding European Public Assessment Report (EPAR) will be made available by the EMEA.

Referrals

Further to Italy's suspension of the marketing and use of the influenza B vaccine HibTITER, a referral under Article 15a of Council Directive 75/319, as amended, was made by Italy.[1]

A procedure under Article 12 of Council Directive 75/319/EEC as amended, has been initiated by France. This procedure relates to terfenadine-containing medicinal products, the marketing of which have been suspended by France and Luxembourg.

In both referral procedures the CPMP will analyse very carefully the reasons for these national measures and will give the marketing authorisation holders an opportunity to attend a CPMP hearing. Adoption of the CPMP Opinion on HibTITER is scheduled for April and the Opinion on terfenadine-containing products is scheduled for June.

Mutual Recognition

The Committee noted that 4 new mutual recognition procedures have been recently finalised as well as 4 type I and 4 type II variation procedures.

No new arbitration issues were raised.

[1] A CPMP Position Statement on HibTITER was adopted in January 1997 and is available on request.

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The status as of procedures under mutual recognition is as follows:

| Year | 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* |
|---|---|---|---|---|---|---|---|
| 1995/96 | 94 | - | 67 | - | 91 | - | 3 |
| 1997 | 11 | 31 | 15 | 4 | 8 | 61 | 0 |

* two for full applications, one for variations

Scientific advice

The CPMP adopted one new Scientific Advice by consensus which brings the total number adopted by the Committee to 27.

Working Parties

The CPMP heard reports from its Quality, Safety, Efficacy and Pharmacovigilance Working Parties. The CPMP also prepared for the forthcoming ICH meeting (Steering Committee and Expert Working Groups) in March 1997 in Narita, Japan.

The CPMP received a report from its Biotechnology Working Party which met on 10-12 February 1997 with a special expert group on BSE. The CPMP "Note for Guidance" on "Minimising the risk of transmitting agents causing spongiform encephalopathy via medicinal products" has been subject to extensive discussion during the last year. The Committee hopes to be able to take a position on the current draft revision of this Note for Guidance at its March meeting.

The following document was adopted:

- Position paper on replacement of animal studies by in vitro models (CPMP/SWP/728/95).

The following documents were released to interested parties for a 6 months consultation period:

- Note for Guidance on the clinical investigation of medicinal products in the treatment of schizophrenia (CPMP/EWP/559/95).
- Note for Guidance on pre-clinical pharmacological and toxicological testing of vaccines (CPMP/SWP/465/95).

In addition, the following ICH topic step 2 guideline was released to interested parties for a 3 month consultation period:

- Statistical principals for clinical trials (ICH topic E9: CPMP/ICH/363/96).

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

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ANNEX I to **CPMP -Feb. 97**
**Press Release**

# CENTRALISED APPLICATIONS TO THE EMEA

| | EX - CONCERTATION | | NEW CENTRALISED | | TOTAL * |
|---|---|---|---|---|---|
| | *Part A* | *Part B* | *Part A* | *Part B* | |
| **APPLICATIONS SUBMITTED SINCE 1.1.95** | 9 | 9 | 22 | 40 | 80 |
| **WITHDRAWN** | 0 | 4 | 0 | 2 | 6 |
| **REVIEW ONGOING** | 0 | 0 | 10 | 22 | 32 |
| **OPINIONS GIVEN BY CPMP** | 9 | 5 | 12 | 16 | 42 |
| **MARKETING AUTHORIZATION GRANTED BY COMMISSION** | 9 | 4 | 4 | 12 | 29 |

** 42 Opinions corresponding to 36 substances*

| | PENDING | | FINAL | | TOTAL |
|---|---|---|---|---|---|
| | *Part A* | *Part B* | *Part A* | *Part B* | |
| **VARIATIONS TYPE I** | 5 | 4 | 17 | 11 | 37 |
| **VARIATIONS TYPE II** | 0 | 9 | 4 | 9 | 22 |
| **SCIENTIFIC ADVICE** | 6 | | 27 | | 33 |

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ANNEX II to **CPMP -Feb. 97**
**Press Release**

## Medicinal Products granted a Community Marketing Authorisation under the Centralised Procedure

Status: 19 February 1997

| **Product**<br>a) Brandname<br>b) INN<br>c) Part A/B | **Company**<br>a) Name<br>b) Origin | **Therapeutic Area**<br>a) ATC<br>b) Indication | **Presentation**<br>a) Form<br>b) Dose<br>c) Number of Presentations | **EMEA/CPMP**<br>a) Validation<br>b) Opinion<br>c) Active Time<br>d) Clock stop | **Commission**<br>a) Date of decision<br>b) Date of notification<br>c) OJ No. |
|---|---|---|---|---|---|
| a) **Twinrix paediatric**<br>b) comb. vaccine<br>c) Part A | a) SmithKline Beecham<br>b) BE | a)<br>b) Immunisation against Hepatitis A/B in children | a) Suspension for injection<br>b)<br>c) 5 Presentations | a) 21.05.96<br>b) 16.10.96<br>c) 132 Days<br>d) 35 Days | a) 10.02.97<br>b)<br>c) |

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