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

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CPMP/351/96

PRESS RELEASE

The Committee for Proprietary Medicinal Products (CPMP) held its 15th plenary meeting on 16-18 April 1996 at the EMEA.

Centralised Procedures

The Committee adopted a positive opinion by consensus for a Part B anti-HIV medicinal product. The application for this new centralised procedure had been submitted in July 1995 and the total review time by the CPMP was 152 days.

A total of 15 positive opinions have now been adopted by consensus by the CPMP since May 1995 (5 new centralised procedures and 10 ex-concertation procedures).

One new application under the centralised procedure has been assigned to a Rapporteur and a Co-Rapporteur following confirmation of Part B status.

Drug Safety

An ad hoc group of experts on bovine spongiform encephalopathy (BSE), together with representatives of the Committee for Proprietary Medicinal Products (CPMP) and the Committee for Veterinary Medicinal Products (CVMP) and members of the Biotechnology Working Party met to consider specific questions raised by the European Commission services concerning the potential risk associated with medicinal products in relation to BSE.

Their report was considered and adopted by the CPMP and the final EMEA Opinion was forwarded to the Commission.

The Committee adopted a Position Statement on oral contraceptives containing Desogestrel or Gestoden which is attached to the press release.

The Committee also adopted a Position Statement on calcium antagonists, further to discussions in the Pharmacovigilance Working Party on recent epidemiological evidence which suggested that such substances may be associated with an increased risk of cardiovascular events and mortality. The Position Statement included additional warnings and contra-indications. The report will be communicated to Marketing Authorisation Holders by the national competent authorities of the Member States.

Scientific Advice

The CPMP adopted an additional scientific advice by consensus for a new active substance.

Mutual Recognition

The first Opinion in an arbitration referred to the EMEA under the Mutual Recognition procedure was adopted by the CPMP (Article 13 of Council Directive 75/319 EEC, as amended). This Opinion, in favour of granting the Marketing Authorisation, will be forwarded to the Commission.

So far 21 (new) Mutual Recognition procedures have been finalised without the need for arbitration, in addition to which 27 type I and 25 type II variations to products previously authorised under the concertation procedure have been handled without referral for arbitration.

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Multi-state Procedures

The Committee adopted by consensus a positive opinion for one (non-binding) Multi-state procedure, to be forwarded to the Member States competent authorities.

CPMP Guidance

The guideline “Testing and licensing criteria for fixed combination medicinal products” was adopted and will come into operation in October 1996 (CPMP/240/95).

The guideline on “Non-clinical testing of substances with long-term marketing experience (old substances)” was released for consultation until 18 June 1996 (CPMP/SWP/799/95.Rev. 4).

Communication with interested parties

Continuing the CPMP’s intention to further exchanges of views with interested parties, a break-out session was held with the “European AIDS Treatment Group”.

This was followed in plenary session by presentations from and discussions with senior representatives from Europe on the Delta Studies and from the US FDA on their assessment of anti-retroviral drugs.

The EMEA hosted a seminar on 18-19 April 1996 organised and sponsored by the European Commission with government experts from Russia, and representatives of the European pharmaceutical industry.

Rolf Bass

Prof. Rolf Bass
Head of Unit

This press release and other documents are available on the Internet (http://www.eudra.org/w3/emea.html)

Encl. · Position Statement on oral contraceptives containing Desogestrel or Gestoden.