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

CPMP/832/95
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PRESS RELEASE

1. The Committee for Proprietary Medicinal Products (CPMP) held its plenary meeting on 21-22 November 1995 at the EMEA.

2. **Centralised Procedures:** The Committee adopted (3) positive opinions by consensus for one new active substance (ex-concertation procedure) which will be forwarded to the Commission shortly. Altogether, EMEA opinions on 7 new active substances (from ex-concertation procedures) have been adopted, by consensus, since May 1995, and transmitted to the Commission for implementation, including Gonal-F which was authorised by the European Commission on 23 October 1995.

   The Committee appointed a Rapporteur and Co-Rapporteur for centralised applications concerning 4 new active substances which are expected for submission to the EMEA in early 1996. In total in 1995, 29 new applications under the Centralised Procedure have now been assigned to Rapporteurs/and Co-Rapporteurs following identification (10 List A and 19 List B).

3. **Multi-State Procedures:** The Committee adopted positive opinions on five (non-binding) multi-state procedures. These opinions are added to the 36 previous positive opinions, which have been forwarded to the Member State competent authorities for granting marketing authorisation (now totalling 41).

4. **ICH:** The CPMP heard a report from an ICH-CPMP co-ordination meeting, and their joint discussion with EFPIA representatives and experts, both held on 15 November 1995 at Canary Wharf in preparation for the upcoming ICH3 Congress in Yokohama, Japan.

5. **CPMP Guidelines:** The Committee approved four clinical guidelines:

   - "Clinical requirements for locally applied, locally acting products containing known constituents" (CPMP/239/95 final)
   - "Antiarrythmic medicinal products" (CPMP/237/95 final)
   - "Clinical investigation of drugs for the treatment of chronic peripheral arterial occlusive disease" (CPMP/233/95 final)
   - "Clinical trials on medicinal products in the treatment of cardiac failure" (CPMP/235/95)

   which will come into operation in June 1996.

6. **Working Parties:** The Committee welcomed, in principle, the creation of a new EMEA Working Party on the Co-ordination of Inspections, to advise, in particular, the CPMP on the co-ordination of inspections for centralised procedures. Until now, 9 such inspections have been performed by the competent authorities, and 6 more have been deemed necessary by the CPMP for the next three months.

   The CPMP heard reports from the Biotechnology Quality Working Party, Pharmacovigilance Working Party, Efficacy Working Party, Quality Working Party and the Safety Working Party, dealing mainly with ICH issues.

7. The Press Release as well as other general information concerning the EMEA (e.g. including the European Public Assessment Report for Gonal-F) are also accessible via the internet:

- **http://www.eudra.org**

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