The European Agency for the Evaluation of Medicinal Products
Technical Co-ordination Unit

London, 27 October 1995
CPMP/PhV/696/95

POSITION STATEMENT OF THE CPMP ON ORAL CONTRACEPTIVES

CONTAINING GESTODENE OR DESOGESTREL

Background Summary

On 17 October 1995 the attention of the CPMP was drawn by the British and the German members to three independently conducted epidemiological studies about to be completed or published:

- a multinational study carried for the World Health Organisation;
- a cohort study based on record linkage carried out by Prof. H. Jick;
- a transnational study carried out by Prof. W.O. Spitzer.

During its plenary session, on 17 and 18 October, the CPMP held a preliminary discussion and heard the investigators involved in these three studies.

As a consequence the CPMP members were asked to analyse the data circulated and forward their comments to the EMEA Secretariat (H/CPMP/657/95) and national competent authorities were asked to wait until further common agreement had been reached by the CPMP before taking any national position.

The three main companies concerned (Organon, Schering and Wyeth) were asked to provide the EMEA with any scientific material related to the risk of 'third generation' oral contraceptive use containing gestodene or desogestrel (H/CPMP/658/95) and were invited to a hearing in the afternoon of 26 October 1995 and presented their analysis of the data to the CPMP ad hoc Working Party.

The CPMP held a special meeting on the 27 October 1995 at the EMEA and considered a written assessment report from its ad hoc working party (CPMP/PhV/690/95 Rev.5).

Position Statement

The CPMP, on the basis of Article 8 of Council Directive 75/319/EEC of 20 May 1975, as amended, has adopted the following position statement on the basis of the appended assessment report:

1. In view of its benefit/risk re-assessment, the CPMP did not consider appropriate to withdraw combined oral contraceptives containing gestodene or desogestrel.

2. The CPMP has taken note of the commitments of the three investigator teams to further analyse their data base, as well as performing a new study concerning acute myocardial infarction within the next three to four months.

3. The CPMP requested the three companies to provide further data before the end of 1995.

4. The CPMP will review these data no later than six months from the date of this position statement.

5. Messages to Doctors/Users should be based on the following:

- Contra-indications of combined oral contraceptives include a history of, or existing venous thromboembolic, cerebrovascular or cardiovascular diseases

- Known risk factors for venous thromboembolism include obesity (as defined as a body mass index greater than thirty - measured as weight in Kg/m^2), varicose veins, or a family history of venous thrombosis

- The risk of venous thromboembolic events with all combined oral contraceptives is still substantially less than that in pregnancy.

6. The CPMP asked the EMEA secretariat to immediately communicate the present position statement to :

- the 15 national competent authorities responsible for the Marketing Authorisations of these products;

- the three companies mentioned above;

- the European Commission.

7. The CPMP asked its chairman to make this position statement available to the public.