I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Orion Corporation, Finland submitted on 4 April 1997 to the European Agency for the Evaluation of Medicinal Products (EMEA), an application to obtain Marketing Authorisation for the medicinal product Comtess tablets 200 mg in accordance with the Centralised Procedure falling within the scope of Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Dr. E. Alhava Co-Rapporteur: Mrs. J. Genoux-Hames

Licensing status

The product was not licensed in any country at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 18 April 1997.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 26 June 1997. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 27 June 1997
- During the CPMP plenary meeting on 23 September 1997, the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the Company on 23 September 1997.
- The company submitted the responses to the consolidated list of questions on 6 February 1998.
- The Rapporteur/Co-Rapporteur circulated the joint assessment report on the company's responses to the list of questions to all CPMP Members on 27 March 1998.
- A hearing was held on 26 May 1998, at the CPMP meeting to address the remaining outstanding issues. This resulted in amendments of the Summary of Product Characteristics, Package Leaflet and Labelling.
- The CPMP, during its meeting on 26 May 1998 discussed the recommendations presented by the Rapporteur, considering the responses provided by the company were satisfactory. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet texts.
- The CPMP during its May meeting, issued a positive opinion (majority) for granting a Marketing Authorisation to Comtess 200 mg film coated tablets, on 27 May 1998
- The CPMP opinion was forwarded, in all official languages of the European Union, to the European Commission which adopted the corresponding Decision on 16 September 1998.