I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ares-Serono (Europe) Ltd. submitted on 29 September 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Ovitrelle 250 micrograms, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993, as amended.
The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Dr. Hans van Bronswijk
Co-Rapporteur Prof. Rolf Bass

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 22 October 1999.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 4 January 2000. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 4 January 2000.
- The Rapporteur's and Co-Rapporteur's draft list of question was circulated to all CPMP Members on 11 February 2000.
- During the meeting on 15-17 February 2000 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 17 February 2000.
- The company submitted the responses to the consolidated list of questions on 16 August 2000.
- The Rapporteur and Co-Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 25 September 2000.
- During the meeting on 17-19 October 2000 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Ovidrelle 250 micrograms on 19 October 2000.