BACKGROUND INFORMATION ON THE PROCEDURE

1. SUBMISSION OF THE DOSSIER

The company Serono Laboratories (UK) Limited submitted an Application to all EU Member States for Gonal-F 75 IU and 150 IU through the Concertation Procedure (No. 71) in December 1993, which was validated by the Member States in January 1994.

In application of art.2 of Directive 93/41/EEC on 13 January 1995, the company, Serono Laboratories (UK) Ltd transferred to the European Agency for the Evaluation of Medicinal Products, into the new centralised procedure, the application for marketing authorisation for r-hFSH (Gonal-F) falling within the scope of Part A of the Annex to Council Regulation (EC) 2309/93.

The CPMP confirmed the status of the Rapporteur and Co-Rapporteur as well as the evaluation team as follows:
Rapporteur: Dr. Jefferys (United Kingdom)
Co-Rapporteur: Dr. Wathion (Belgium)

Licensing Status: the product was licensed in Sweden and Finland before their accession to the EU. The new EU authorisation will replace in these two Member States the existing ones. A New Drug Application was filed on 16 September 1993 in USA.

1.2. STEPS TAKEN FOR THE ASSESSMENT OF THE PRODUCT

- The Rapporteur (ANNEX I) and Co-Rapporteur (ANNEX II) initial assessment reports were circulated to all Members of the previous CPMP on 29 April 1994.

- The consolidated list of comments for part III and IV was sent by the Rapporteur to the company in July 1994 and for part II in August 1994.

- The company submitted to all the Member States further information addressing the consolidated comments on parts II, III, and IV in December 1994.

- The “Response assessment report” was circulated by the Rapporteur to all new Members of the CPMP on 22 February 1995.(ANNEX III).

- The CPMP in March 1995 meeting considered that there were no outstanding pharmacotoxicological questions on part III of the dossier. A single indication was agreed by subcutaneous route of administration only. The unresolved pharmaceutical points were to be discussed at the Biotechnology working party on 6 and 7 April 1995.

- The Rapporteur sent to the company a list of outstanding pharmaceutical points in March 1995, and responses were provided to the Rapporteur in April 1995.

- The ad hoc CPMP Biotech working group during its meeting on 6 and 7 April 1995 gave a favourable opinion on the quality of the product The company committed to provide the CPMP with updated reports on the identified points within the agreed 6 or 12 months time frame.

- Further clinical points for clarification were sent by the Rapporteur to the company on 11 April 1995 and clarified sufficiently by the company within the same month.

- The necessary revision of the Summary of Product Characteristics, User Package Insert and proposed Labelling was submitted in all EU national languages to the EMEA on 12 April 1995.

- The CPMP during its meeting on April 26 and 27, considered that all the clinical and pharmacotoxicological objections were resolved as well as all the major quality objections. The remaining quality points would be addressed according to the timetable agreed with the company.

- At its meeting of May 1995 the CPMP adopted its final - positive - opinion on each of the four presentations for
  GONAL-F by consensus