BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ares-Serono (Europe) Ltd, submitted on 27 June 1996 to the European Agency for the Evaluation of Medicinal Products (EMEA), an application to obtain marketing authorisation for the medicinal product Rebif, in accordance with the Centralised procedure falling within the scope of Part A of the Annex to Council Regulation No. (EC) 2309/93 of 22 July 1993.

The CPMP confirmed the status of the Rapporteur and Co-Rapporteur as follows:

Rapporteur: Dr. P. Sjöberg Co-Rapporteur: Dr. M. Marselos

Licensing status:

A new drug application was pending in the following countries at the time of submission of the application:

Switzerland, Norway, Iceland, Canada

The product was licensed in countries inside and outside the EU at the time of submission of the application:

(For different indications) Italy (27.4.93), Argentina (4.7.94), Hong Kong (8.2.96)

2. Steps taken for the assessment of the product

- The Rapporteur's initial assessment report was circulated to all CPMP Members on 27 September 1996. The Co-Rapporteur's initial assessment report was circulated to all CPMP Members on 27 September 1996.
- During the meeting on 19 November 1996 the CPMP agreed on the consolidated list of questions to be sent to the company on 21 November 1996.
- The final consolidated list of questions was sent to the Company on 21 November 1996.
- The company submitted the responses to the consolidated list of questions on 26 May and on 10 July 1997.
- The Rapporteur circulated the comments on the company's responses to the list of questions to all CPMP Members on 26 August 1997.
- The Biopharmaceutical part of the dossier was discussed at the Biotechnology Working Party meeting on 7 September 1997.
- The CPMP, during its meeting on 22-24 September 1997 discussed the recommendations presented by the Rapporteurs, considering the medicinal product approvable but the responses provided by the company not to be fully satisfactory. A list of additional information to be provided by the company was agreed and the need for an oral explanation discussed and in principle agreed.
- The CPMP, during its meeting on 22-24 September 1997 agreed on the conduct of a Good Clinical Practice compliance verification of the main clinical trial.
- A second CPMP list of points for clarification was sent to the Applicant on 25 September 1997.
- The company provided additional information on 10 November 1997.
- The Rapporteurs' assessment of the additional information provided by the Applicant was circulated on 8 December 1997.
- During the Biotechnology Working Party meeting held on 9-10 December 1997 the remaining points were discussed and from the quality stand point a positive recommendation for the granting of a marketing authorisation was adopted.

- The CPMP, during its meeting on 15-17 December 1997 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. The Package Leaflet text was amended accordingly.
- The CPMP during its meeting on 15-17 December 1997, in the light of the current scientific standards recommended the granting of a Marketing Authorisation under exceptional circumstances, in accordance with Article 13 (2) of Council Regulation (EEC) No 2309/93 and Part 4 G of the annex to Council Directive 75/318/EEC Rebif.
- The CPMP with reference to Part 4 G of the annex to Council Directive 75/318/EEC, considered that in the present state of scientific knowledge, comprehensive information on the safety and efficacy of the medicinal product cannot be provided by the applicant.