BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The Company Pharmacia Enterprises S.A. submitted on 12 March 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Somavert, 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.

The Rapporteur and Co-Rapporteur appointed by the CPMP and the evaluation teams were:
Rapporteur: Dr. Eric Abadie Co-Rapporteur: Dr. Gonzalo Calvo Rojas

Orphan Medicinal Product:
Somavert was designated as orphan medicinal product EU/3/01/023 on 14 February 2001 in the following indication: treatment of acromegaly.

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 29 March 2001.
- During the meeting on 26-28 June 2001 the CPMP adopted the Rapporteur's and the EMEA Secretariat's proposal that no inspection(s) or sampling and testing had to be carried out before the assessment of Somavert is complete.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 5 July 2001 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 12 July 2001 (Annex 2)
- During the meeting on 17-18 July 2001 the Biotechnology Working Party agreed in their report to the CPMP on the main quality issues following initial assessment to be included in the List of Questions (Annex 3).
- During the meeting on 24-26 July 2001 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 26 July 2001 (Annex 4).
- The company submitted the responses to the CPMP consolidated List of Questions on 28 January 2002.
- The response Assessment Report on the company's responses to the List of Questions was circulated to all CPMP members on 4 April 2002 (Annex 5).
- During the meeting on 23-25 April 2002 the CPMP adopted a List of Outstanding Issues to be addressed during an oral explanation and in writing (Annex 6).
- The company submitted the responses to the CPMP List of Outstanding Issues on 28 May 2002.
- During the meeting on 25-27 June 2002, the CPMP requested a GMP inspection for the manufacturing site for the active substance: Diosynth RTP, Inc.
- The response Assessment Report on the company's responses to the List of Outstanding Issues was circulated to all CPMP members on 1 July 2002 (Annex 7).
- The company submitted their responses to remaining issues on 15 July 2002.

- During the meeting on 23-25 July 2002 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 Pharmacia Enterprises S.A. on 25 July 2002.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 13 November 2002.