BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant ASTA Medica Aktiengesellschaft submitted on 2 February 1998 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Cetrotide, in accordance with the centralised procedure, falling within the scope of Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Professor A. Hildebrandt Co-Rapporteur: Dr. D. Jefferys

Licensing status:

The product was not licensed in any country inside or outside the EU at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 27 February 1998.
- During its meeting on 21-22 April 1998, the CPMP agreed that a GMP inspection of the manufacturing site was not necessary.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 18 May 1998.
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 11 May 1998.
- During its meeting on 23-25 June 1998, 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 25 June 1998.
- The company submitted the responses to the consolidated list of questions on 12 October 1998.
- The Rapporteur and the Co-Rapporteur circulated the joint assessment report on the company's responses to the list of questions to all CPMP Members on 26 November 1998.
- During its meeting on 15-17 December 1998, the CPMP agreed on a list of outstanding issues (inferior pregnancy rate, baby data of the cryopreservation programme, luteal support and effect duration, stimulation with recombinant FSH, histamine release, and SPC wording) to be addressed by the company in an oral explanation. A hearing was held at the CPMP meeting on 15 December 1998.
- The CPMP, during their meeting on 15-17 December 1998, considered the responses provided by the company and discussed the recommendations presented by the Rapporteur. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet texts.
- The applicant provided a letter of undertaking on the follow-up measures to be fulfilled as requested by the CPMP (on remaining quality issues), dated 16 December 1998.
- During the meeting on 15-17 December 1998, 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 for Cetrotide 0.25 mg and 3 mg powder and solvent for solution for injection on 17 December 1998.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 13 April 1999.