BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Aventis Pharma S.A. (France) submitted on 31 July 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Dynepo, 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 CHMP were:

Rapporteur: Dr. F. Rotblat Co-Rapporteur: Dr. P. Salmon

Licensing status:

A new drug application was filed in the following countries: USA (28 July 2000).

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 26 September 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 6 December 2000. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 5 December 2000.
- During the meeting on 16-17 January 2001 the BWP prepared a Report to the CPMP on the quality issues related to this application.
- During the meeting on 23-25 January 2001 the CPMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 26 January 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 6 July 2001.
- The summary report of the inspection carried out at the manufacturing site(s) between 3-6 July 2001 of the Lonza Biologicals (USA) site and between 13-15 June 2001 of the Grupo Lepetit SpA (Italy) site were issued on 24 August 2001 and 27 August 2001 respectively.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 22 August 2001.
- During the meeting on 11-12 September 2001 the BWP prepared an Interim Report to the CPMP on the outstanding quality issues related to this application.
- During the meeting on 18-20 September 2001 the CPMP agreed on the List of outstanding questions to be addressed during an oral explanation. The List of outstanding questions was sent to the applicant on 20 September 2001.
- The company submitted the responses to the List of outstanding questions on 26 September 2001 and 12 November 2001.

- The Rapporteur circulated the Assessment Report on the company's responses to the List of outstanding questions to all CPMP members on 20 November 2001. The Rapporteur indicated that there was no need for an oral explanation.

- The Rapporteur circulated on 30 November 2001 the final AR of outstanding issues arising from the Assessment Report of 19 November 2001.

- During the meeting on 3 –5 December 2001 the BWP prepared the Final Report to the CPMP on the outstanding quality issues related to this application.

- During the meeting on 11-13 December 2001 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 Dynepo on 13 December 2001.