BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Aventis Pasteur MSD S.N.C., France submitted on 8 July 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Hexavac, 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 were:

Rapporteur: Dr. M. Haase Co-Rapporteur: Dr Pasqualino Rossi

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 30 July 1999.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 6 October 1999. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 8 October 1999.
- The BWP during its meeting of 9-10 November 1999, adopted the BWP recommendation to be transmitted to the CPMP for endorsement.
- During the meeting on 16-18 November 1999 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 company on 18 November 1999.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 2 March 2000.
- The Rapporteur's/Co-Rapporteur's Joint Assessment Report on the Applicant's Response to CPMP's consolidated List of Questions was circulated to all CPMP members on 20 April 2000.
- The BWP during its meeting of 16-17 May 2000, adopted the BWP recommendation to be transmitted to the CPMP for endorsement.
- An ad hoc expert group meeting on clinical issues was held on 22 May 2000 and a report from this meeting was circulated to all CPMP members on 23 May 2000.
- A list of outstanding issues was identified by the CPMP at its meeting on 23-25 May 2000.
- The Rapporteur´s/Co-Rapporteur´s pharmaceutical Joint Assessment Report on CPMP´s List of Outstanding Issues was circulated to the CPMP and all BWP members on 14 June 2000.
- The BWP during its meeting of 20-21 June 2000, adopted the BWP recommendation to be transmitted to the CPMP for endorsement.
- The company, Aventis Pasteur MSD S.N.C. provided on 29 June 2000, a letter of undertaking on the follow-up measures (pharmaceutical and clinical issues), to be fulfilled as requested by the CPMP.

- During the meeting on 27-29 June 2000 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 Hexavac on 29 June 2000.