BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Wyeth Lederle Vaccines S.A., Belgium submitted on 12 October 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Prevenar, through the centralised procedure. After agreement by the CPMP on 18-20 May 1999, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

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

Rapporteur: Daniel Brasseur Co-Rapporteur: Per Nilsson

Scientific Advice:

The applicant did not seek scientific advice at the CPMP.

Licensing status:

Prevenar has been given a Marketing Authorisation in USA on 17 February 2000.

2. Steps taken for the assessment of the product

- The procedure started on 19 November 1999.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 28 January 2000. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 4 February 2000.
- The BWP during its meeting of 7-8 March 2000, adopted the BWP recommendation to be transmitted to the CPMP for endorsement.
- During the meeting on 14-17 March 2000 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 17 March 2000.
- The company submitted the responses to the CPMP consolidated List of Questions on 17 May 2000.
- The favourable summary report of the inspection carried out at the manufacturing site between 19-20 April 2000 of the Wyeth Lederle Vaccines, 401 North Middletown Road, NY 10965-1299, Pearl River, USA was issued by the Medicines Control Agency, Market Towers, 1 Nine Elms Lane, London SW8 5 NQ, and United Kingdom on 13 June 2000.
- The EMEA circulated the Rapporteur's and Co-Rapporteur's joint assessment report on the company's responses to the List of Questions to all CPMP members on 3 July 2000.
- The BWP during its meeting of 20-21 July 2000, adopted the BWP recommendation to be transmitted to the CPMP for endorsement.
- The CPMP in its meeting of 25-27 July 2000 adopted the BWP recommendation and the list of outstanding issues and agreed that an oral explanation would be necessary to address them.
- On 27 July 2000 the company requested a "stop-of-the-clock" in order to prepare for the oral explanation. The revised list of outstanding questions to be addressed at the oral explanation was sent to the company on 27 July 2000.
- The company provided supplementary written information addressing the outstanding questions to the CPMP members on 23 August 2000.
- The BWP during its meeting of 12-13 September 2000, adopted the BWP recommendation to be transmitted to the CPMP for endorsement.

- The fabourable summary report of the inspection carried out at the manufacturing site between 17-18 April 2000 of Wyeth Lederle Vaccines, 4300 Oak Park, NC 27330, Sanford, USA, was issued by the Medicines Control Agency, Market Towers, 1 Nine Elms Lane, London SW8 5 NQ, United Kingdom on 14 September 2000.
- During the CPMP meeting on 20 September 2000, outstanding issues were addressed by the applicant during a hearing before the CPMP.
- The EMEA circulated the Rapporteur's and Co-Rapporteur's joint assessment report following the applicants hearing to all CPMP members on 4 October 2000.
- The company, Wyeth Lederle Vaccines S.A., provided on 13 October 2000, a letter of undertaking on the follow-up measures to be fulfilled as requested by the CPMP.
- During the meeting on 17-19 October 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 to Prevenar on 19 October 2000.