BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Pasteur Mérieux MSD, France, submitted on 10 February 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for COMVAX (later changed to PROCOMVAX), 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. E. Abadie

Licensing status

PROCOMVAX was given a Marketing Authorisation in United States of America on 2 October 1996.

2. Steps taken for the assessment of the product

- The procedure started on 25 February 1998.
- The Rapporteur's initial assessment report was circulated to all CPMP Members on 8 May 1998.
- The Co-Rapporteur's initial assessment report was circulated to all CPMP Members on 12 May 1998.
- The BWP during its meeting of 16-17 June 1998, discussed the major pharmaceutical objections and adopted a BWP Report to be transmitted to the CPMP.
- The CPMP, during its meeting of 23-24 June 1998, adopted the CPMP consolidated list of questions to be sent to the company. Also in this meeting, objections were raised with respect to the acceptability of the proposed tradename COMVAX.
- The CPMP consolidated List of Questions was sent to the company on 25 June 1998.
- Merck & Co. Inc. facilities in West Point, Pennsylvania, USA (manufacturer of the active substances and finished product), were inspected by the Dutch Health Care Inspectorate and the German pharmaceutical expert on 31 August to 3 September 1998. Major deficiencies were identified for which an acceptable action plan to correct the deficiencies was requested.
- The company submitted the responses to the consolidated list of questions on 9 September 1998.
- The Rapporteur's and Co-Rapporteur's joint assessment report on the company's responses to the list of questions was circulated to all CPMP Members on 19 October 1998.
- The objection to the tradename was addressed by the company in their letter of 16 October 1998 which was considered by the CPMP in its meeting of 20-22 October 1998.
- On 19 October 1998, the company submitted a proposal for a new name – PROCOMVAX. The new name was forwarded to the national contact points to be checked.
- On 17 November 1998, the Dutch Health Care Inspectorate issued a favourable inspection report in which it was concluded that the manufacturer of the active substances and finished product of the combined vaccine, Merck & Co. Inc. West Point, USA, complied with the EU GMP rules.

- The CPMP in its meeting of 17-19 November 1998 discussed the outstanding clinical issues and agreed that an oral explanation would be necessary to address them.
- On 20 November 1998, the company requested a "stop-of the-clock" in order to prepare for the oral explanation. The list of outstanding questions to be addressed at the oral explanation was sent to the company on 20 November 1998.
- The company provided supplementary written information addressing the outstanding questions to all the CPMP members on 27 November 1998.
- On 15 December 1998, the company addressed the outstanding questions at an oral explanation.
- The CPMP during its meeting of 15-17 December 1998, discussed the outstanding questions addressed during the oral explanation by the company. It was the view of the CPMP that the major safety issue had not been satisfactorily resolved and that further explanation regarding this issue was required.
- On 16 December 1998, the company requested a "stop-of the-clock" in order to provide further information by written explanation. The list of outstanding issue to be addressed by written explanation was sent to the company on 18 December 1998.
- On 4 January 1999, the company submitted further written explanation in response to the outstanding safety issue, to all CPMP members.
- The Co-Rapporteur's assessment of the written explanation in response to the outstanding safety issue was circulated to all CPMP members on 18 January 1999.
- The Rapporteur's assessment of the written explanation in response to the outstanding safety issue was circulated to all CPMP members on 19 January 1999.
- The CPMP during its meeting on 26-27 January 1999, discussed the written explanations on the outstanding questions from the company. Amendments to the Summary of Product Characteristics, and the follow-up measures to be undertaken by the company were also discussed.
- The company, Pasteur Mérieux MSD, provided on 26 January 1999, a letter of undertaking on the follow-up measures (pharmaceutical and clinical issues), to be fulfilled as requested by the CPMP.
- During the CPMP meeting of 26-27 January 1999, the CPMP, in the light of the overall data submitted, the follow-up measures undertaken by the company and the scientific discussion within the Committee, issued a positive opinion for the granting of a Marketing Authorisation for PROCOMVAX on 27 January 1999.