BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company SmithKline Beecham Biologicals S. A., submitted on 2 August 1995 to the European Agency for the Evaluation of Medicinal Products (EMEA), an application to obtain marketing authorisation for the medicinal product TWINRIX Adult, in accordance with the Centralised procedure falling within the scope of Part A of the Annex to Council Regulation No. (EC) 2309/93 of 22 July 1993.

The CPMP confirmed the status of the British Rapporteur and of the Irish Co-Rapporteur:

Rapporteur: Dr. D. Jefferys Co-Rapporteur: Dr. M. Teeling

2. Steps taken for the assessment of the product

- The Co-rapporteur's initial full assessment report was circulated to all members of the CPMP on 9 November 1995.
- The Rapporteur's initial full assessment report was circulated to all members of the CPMP on 11 November 1995.
- The CPMP in its meeting on 19-20 December 1995, discussed the major issues related to this application; in particular the rationale for the clinical need for such a combined vaccine. The consolidated list of questions to be sent to the company was adopted.
- The CPMP consolidated list of questions was sent to the company on 21 December 1995.
- The company submitted the responses to the CPMP consolidated list of questions on the 13 March 1996.
- The Rapporteur's assessment report on the company responses was circulated to all CPMP members on 15 April 1996.
- The Co-rapporteur's assessment report on the company responses was circulated to all CPMP members on 18 April 1996.
- Member States comments on the Rapporteur and Co-rapporteur's assessment reports were received up to 10 May 1996.
- A meeting was held between the Rapporteur and Co-rapporteur on 13 May 1996 to discuss the outstanding points. A breakout session on pharmaceutical matters was considered to be necessary to further discuss these outstanding points.
- The company provided additional information addressing the outstanding points on the 15 May 1996.
- During the CPMP meeting on 20-22 May 1996, a breakout session on pharmaceutical matters took place, where the company in response to the remaining outstanding issues gave oral explanations.
- The outcome of the breakout session was circulated at the CPMP meeting on 21 May 1996.
- The CPMP in its meeting on 20-22 May 1996, considered the responses provided by the company to be adequate and unanimously granted a positive opinion for Twinrix Adult, monodose vial and syringe presentations.