BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant SmithKline Beecham Biologicals S.A., Belgium, submitted on 1 July 1999 to the European Agency for the Evaluation of Medicinal Products (EMEA), an application to obtain a marketing authorisation in accordance with the Centralised Procedure for the medicinal product Infanrix hexa (combined Diphtheria, Tetanus, acellular Pertussis, recombinant Hepatitis B, inactivated Poliovirus and Haemophilus influenzae type b vaccine) falling within the scope of Part A of the Annex to Council Regulation No (EC) 2309/93.

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

Rapporteur:	Dr. Daniel Brasseur	Co-Rapporteur:	Dr. Manfred Haase

Licensing status:

The product was not licensed in any country inside or outside the EU 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 members of the CPMP on 11 October 1999).
- The Co-Rapporteur's first assessment report was circulated to all members of the CPMP on 6 October 1999 In its meeting on 9-10 November 1999, the Biotechnology Working Party (BWP) discussed the draft list of questions on Part II of the dossier and endorsed the (Co)-Rapporteurs' recommendation to the CPMP. A BWP report was prepared for adoption at the CPMP meeting on 16-18 November 1999.
- During its meeting on 16-18 November 1999, the CPMP agreed on the consolidated list of questions to be sent to the applicant on 18 November 1999.
- The applicant submitted the responses to the consolidated list of questions on 23 December 1999.
- The Rapporteur and the Co-Rapporteur circulated the joint response assessment report on the applicant's responses to the consolidated list of questions to all CPMP members on 22 February 2000.
- During its meeting on 7-8 March 2000, the Biotechnology Working Party (BWP) discussed the draft list of outstanding issues on Part II of the dossier and endorsed the (Co)-Rapporteur's recommendation to the CPMP. A BWP report was prepared for adoption at the CPMP meeting on 14-16 March 2000.
- During its meeting on 14-16 March 2000, the CPMP agreed on a list of outstanding issues to be addressed by the company in writing (quality and safety issues) and during an oral explanation (safety issues) held on 24 May 2000.
- The applicant submitted the written responses to the outstanding issues on 3 May 2000.
- The Rapporteur circulated a further assessment report, taking into account the company's

responses on the outstanding quality and safety issues, to all CPMP members on 12 May 2000.

- 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.

- The applicant submitted updated information relating to Part II.V of the dossier to all CPMP Members on 15 June 2000.

- The Rapporteur's assessment report on the supplementary information relating to Part II.V was circulated on 15 June 2000.

- During its meeting on 20-21 June 2000, the Biotechnology Working Party (BWP) discussed the Rapporteur's assessment report on the supplementary information relating to Part II.V of the dossier and endorsed a recommendation to the CPMP. A BWP report was prepared for adoption at the CPMP meeting on 27-29 June 2000.

- 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 Infanrix hexa on 29 June 2000. The applicant agreed to submit additional information regarding quality/clinical/safety data within the defined timeframe.