BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant GlaxoSmithKline Biologicals s.a. submitted on 4 June 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Ambirix, 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. F. Rotblat Co-Rapporteur: Dr. D. Lyons

Scientific Advice:

The applicant did not seek scientific advice at the CPMP.

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 19 June 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 7 September 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 31 August 2001.
- During the meeting on 16-18 October 2001 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 18 October 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 11 March 2002.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 8 April 2002 (Annex 4).
- During the meeting on 28-30 May 2002 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 Ambirix on 30 May 2002.