BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant submitted on an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Ytracis, through the centralised procedure. After agreement by the CPMP on 23 March 2002 , 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: Dr B. van Zwieten-Boot Co-Rapporteur: Dr J. Ersbøll

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 22 October 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 16 January 2002. The Co-Rapporteur's first Assessment Report was circulated on 10 January 2002 to all CPMP members.
- During the meeting on 19-21 February 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 21 February 2002.
- The company submitted the responses to the CPMP consolidated List of Questions on 5 July 2002.
- The Rapporteur and Co-Rapporteur circulated their Joint Assessment Report on the company's responses to the List of Questions on 27 August 2002 to all CPMP members.
- During the meeting on 17-19 September the CPMP agreed on the List of Outstanding issues to be sent to the applicant. The final List of Outstanding issues was sent to the applicant on 19 September 2002.
- The company submitted the responses to the CPMP List of outstanding issues on 17 October 2002.
- During the meeting on 19-21 November 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 Ytracis on 21 November 2002.