BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Lilly ICOS Limited submitted on 28 June 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for CIALIS, through the centralised procedure. After agreement by the CPMP on 29 March 2001, 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: Prof. Fernando de Andres-Trelles Co-Rapporteur: Prof. Beatriz Lima

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 17 July 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 24 October 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 1 October 2001.
- During the meeting on 13-15 November 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 15 November 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 13 December 2001.
- An Inspection of the Batch Release Site was not requested.
- The Rapporteur and Co-Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 8 February 2002.
- During the CPMP meeting on 19-21 February 2002, the List of Outstanding Issues to be addressed in writing and during an oral explanation was discussed and agreed by the CPMP.
- The company submitted the responses to the List of Outstanding Issues on 23 May 2002.
- The Rapporteur and Co-Rapporteur circulated the Joint Assessment Report on the company's written responses to the List of Outstanding Issues to all CPMP members on 18 June 2002.
- During the CPMP meeting on 25-27 June 2002, outstanding issues were addressed by the applicant during a hearing before the CPMP.
- During the meeting on 23-25 July 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 for CIALIS on 25 July 2002.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 12 November 2002.