BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Pharma AG submitted on 28 May 2003 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for EMSELEX, through the centralised procedure. After agreement by the CHMP on 20 February 2003, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Prof. Fernando de Andrées-Trelles Co-Rapporteur: Dr. Pieter Neels

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 23 June 2003
- The Rapporteur's first assessment report was circulated to all CHMP Members on 26 September 2003. The Co-Rapporteur's first assessment report was circulated to all CHMP Members on 16 September 2003.
- During the meeting on 21-22 October 2003 the CHMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 23 October 2003.
- The company submitted the responses to the consolidated list of questions on 12 February 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 1 April 2004
- During the CHMP meeting on 20-22 April 2004, the CHMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant.
- The applicant submitted the responses to the List of Outstanding Issues on 7 June 2004.
- During the meeting on 27-29 July 2004, the CHMP, 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 EMSELEX on 29 July 2004.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 22 October 2004.