BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Ltd submitted on 22 December 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Starlix, through the centralised procedure. After agreement by the CPMP on 25 March 1999, 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. Mary Teeling Co-Rapporteur: Prof. Cristina Sampaio

Scientific Advice:
The applicant received Scientific Advice from the CPMP on 18 April 1996. The Scientific Advice pertained to parts II and IV of the dossier.

Licensing status:

Starlix has been given a Marketing Authorisation in Japan in June 1999 under the name Fastic, Starsis.

2 Steps taken for the assessment of the product

- The procedure started on 21 January 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 28 March 2000. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 7 April 2000.
- During the meeting on 23 May 2000 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 company on 24 May 2000.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 10 August 2000.
- The summary report of the inspection carried out between 8-11 August 2000 at the manufacturing site(s) of Novartis Pharma Stein AG, Shcaffhauser Strasse, CH-4332 Switzerland and Konapharma AG, Netzibodenstrasse 23-D, CH-4133 Prattein, Switzerland, was issued on 12 September 2000.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 27 September 2000.
- During the CPMP meeting on 12 December 2000, outstanding issues were addressed by the applicant during a hearing before the CPMP.
- During the meeting on 12-14 December 2000 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion by majority vote for granting a Marketing Authorisation to Starlix on 14 December 2000.