BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Ltd submitted on 17 October 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Trazec, through the centralised procedure. After agreement by the CPMP on 25 March 1999 for nateglinide, 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:

Trazec 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 17 October 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 Trazec on 14 December 2000.

Medicinal product no longer authorised

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