

BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Alcon Laboratories (UK) Ltd submitted on 4 December 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Travatan, through the centralised procedure. After agreement by the CPMP on 27 July 2000, 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 and the evaluation teams were:

Rapporteur: Dr F. Garcia Alonso

Co-Rapporteur: Dr F. Rotblat

Licensing status:

The product was not licensed in any country at the time of submission of the application.

Since then, Travatan has been given a Marketing Authorisation in the USA in March 2001, in Brazil in May 2001 and in Mexico in April 2001.

A new application is pending in Canada.

2. Steps taken for the assessment of the product

- The procedure started on 26 December 2000
- The Rapporteur's first assessment report was circulated to all CPMP Members on 16 March 2001. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 6 March 2001.
- During the meeting on 25 April 2001 the CPMP 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 26 April 2001.
- The company submitted the responses to the consolidated list of questions on 23 May 2001
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 13 July 2001.
- During the meeting on 24-26 July 2001 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 Travatan on 26 July 2001.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 27 November 2001.