I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Alcon Laboratories (UK) Ltd. submitted on 08 March 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Opatanol, through the centralised procedure. After agreement by the CPMP on 25 January 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 and the evaluation teams were:

Rapporteur: Dr. Patrick Salmon Co-Rapporteur: Dr. Mark A. Ainsworth

Scientific Advice:

The applicant received Scientific Advice from the CPMP on 17 July 1996. The Scientific Advice pertained to parts II and IV of the dossier.

Licensing status:

OPATANOL/Patanol has been given a Marketing Authorisation in numerous countries, especially in America, from December 1996.

New applications were filed in other countries outside the EEA.

2. Steps taken for the assessment of the product

- The procedure started on 27 March 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members 15 June 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 08 June 2001.
- During the meeting on 24-26 July 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 26 July 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 30 August 2001.
- The Rapporteur and the CoRapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 17 October 2001.
- During the CPMP meeting on 13-15 November 2001, the CPMP agreed on a List of Outstanding Issues.
- During the CPMP meeting on 11-13 December 2001, outstanding issues were addressed by the applicant during a hearing before the CPMP and a list of remaining issues to be answered in writing was adopted by the CPMP.
- The company submitted the responses to the CPMP list of remaining issues on 4 January 2002.
- The Rapporteur and the Co-Rapporteur circulated the response Assessment Report on the company's responses to the list of remaining issues to all CPMP members on 30 January 2002.
- During the meeting on 19-21 February 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 to OPATANOL on 21 February 2002.
- The CPMP Opinion was forwarded in all official languages of the European Commission, which adopted the corresponding Decision on 17 May 2002.