I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Alcon Laboratories (UK) Ltd submitted on 26 November 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Emadine, through the centralised procedure. After agreement by the CPMP on 20 June 1996, this medicinal product was referred to Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993, as amended.

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

Rapporteur:	Dr E Abadie	Co-Rapporteur:	Mr H Hovgaard, replaced by Dr G Jensen

2. Steps taken for the assessment of the product

- The procedure started on 17 December 1997
- The Rapporteur's first assessment report was circulated to all CPMP Members on 2 March 1998. The Co-rapporteur's first assessment report was circulated to all CPMP Members on 4 March 1998
- During the meeting on 20 – 22 April 1998 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 23 April 1998.
- The company submitted the responses to the consolidated list of questions on 13 July 1998
- The Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP Members on 1 September 1998. Comments from Member States were received by 10 September 1998.
- During the meeting on 15-17 September 1998, the CPMP discussed a number of unresolved issues relating to efficacy and safety of the product and prepared a list of two outstanding issues relating to proof of efficacy, to be addressed by the applicant at an oral presentation. This was communicated to the company on 16 September 1998.
- During the meeting on 20-22 October 1998 the company gave an oral presentation on the outstanding issues, on 20 October 1998.
- The company submitted a letter of undertaking dated 20 October 1998, to provide information as follow-up measures.
- During the meeting on 20-22 October 1998 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 Emadine on 22 October 1998.
- The CPMP opinions were forwarded in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 27 January 1999.