I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Alcon Laboratories (UK) Ltd submitted on 25 November 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Azopt, through the centralised procedure. After agreement by the CPMP on 18 July 1996, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur:	Prof. J.F Olalla Marañon (until 21.10.1999) Dr. C. Avendaño (from 22.10.1999)	Co-Rapporteur:	Dr. E. Abadie

Licensing status:

At the time of the submission Azopt had been given a Marketing Authorisation in 6 countries, including the US.

2. Steps taken for the assessment of the product

- The procedure started on 18 December 1998.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 8 March 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 4 March 1999.
- During the meeting on 20-22 April 1999 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 1999.
- The company submitted the responses to the consolidated list of questions on 7 September 1999.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 28 October 1999.
- During the meeting on 16-18 November 1999 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 Azopt on 18 November 1999.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 9 March 2000.