I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant CibaVision Europe Ltd. submitted on 6 August 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Visudyne, through the centralised procedure. After agreement by the CPMP on 25 March 1999, 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 and the evaluation teams were:

Rapporteur:	Dr E Abadie	Co-Rapporteur:	Dr M Ainsworth (replacing Dr G Jensen)

Licensing status :

The product was not licensed in any country inside or outside the EU at the time of submission of the application. An NDA application was submitted to the FDA on 16 August 1999, 10 days after the EU submission.

2. Steps taken for the assessment of the product

- The applicant's dossier was received on 6 August 1999.
- The procedure started on 27 August 1999.
- The Rapporteur's first assessment report was circulated to all CPMP members on 5 November 1999.
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 8 November 1999.
- During the meeting on 14 – 16 December 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 applicant on 17 December 1999.
- The applicant met with the Rapporteur and Co-Rapporteur at the EMEA on 17 January 2000 in order to clarify certain clinical and pharmaceutical issues in the List of Questions.
- The responses to the List of Questions were submitted on 1 February 2000.
- The Rapporteur circulated the Rapporteur/Co-Rapporteur joint assessment report on the company's responses to the List of Questions to all CPMP Members on 23 March 2000.
- The applicant submitted a revised SPC on 8 April 2000
- During the meeting on 11 – 13 April 2000 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee issued a positive opinion by consensus for granting a Marketing Authorisation for the product Visudyne on 12 April 2000. The Norwegian and Icelandic CPMP Members agreed with this opinion.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 27 July 2000.