BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Alcon Laboratories (U.K.) Ltd. submitted on 22 April 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for DuoTrav, through the centralised procedure.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application

Scientific Advice:
The applicant did not seek scientific advice at the CHMP.

Licensing status:
The product was not licensed in any country at the time of submission of the application.
A new application was filed in the following countries: USA (13/11/03), Australia (08/06/04), New Zealand (14/07/04).

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

Rapporteur: G. Calvo Rojas Co-Rapporteur: K. Broich

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 22 April 2005.
- The procedure started on 18 May 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 5 August 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 29 July 2005.
- During the meeting on 13-15 September 2005, the CHMP 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 16 September 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 16 November 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 3 January 2006.
- During the CHMP meeting on 23-26 January 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant.
- The applicant submitted the responses to the CHMP list of outstanding issues on 30 January 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the list of outstanding issues to all CHMP members on 8 February 2006.
- During the meeting on 20-23 February 2006, the CHMP, 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 DuoTrav on 23 February 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 22 February 2006.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 24 April 2006.