1 BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Elan Pharma International Ltd submitted on 3 June 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Tysabri, 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 received Scientific Advice from the CHMP on 17 October 2002. The Scientific Advice pertained to quality and clinical aspects of the dossier.

Licensing status:
The product was not licensed in any country at the time of submission of the application.

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

Rapporteur: Dr Manfred Haase Co-Rapporteur: Dr P. Rossi

EMEA Product Team Leader: Dr Eric Pelfrene

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 3 June 2004.
- The procedure started on 24 June 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 30 August 2004 . The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 3 September 2004.
- During the meeting on 18-21 October 2004, 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 21 October 2004.
- During the meeting on 15-17 March 2005, the CHMP agreed on an Addendum to the CHMP Day 120 List of Questions to be sent to the applicant. The Addendum to the List of Questions was sent to the applicant on 18 March 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 6 October 2005.
- The following inspections were carried out during the assessment of the application:
  Biogen Idec Inc - 14 Cambridge Center - Cambridge, MA – USA, on 5 – 7 January 2005, by the Dutch Competent Authorities, outcome of the inspection: positive;
  Biogen Idec Inc - One Antibody Way - Oceanside, CA – USA, on 3 January 2005, by the Dutch Competent Authorities, outcome of the inspection: positive;
  Biogen U.S. Limited Partnership - 5000 Davis Drive, Research Triangle Park - NC – USA, on 19 –22 October 2004, by the Dutch Competent Authorities, outcome of the inspection: positive;
  Sicor Pharmaceuticals Inc - 21 Hughes - Irvine, CA – USA, on 25-29 April 2005, by the UK Competent Authorities, outcome of the inspection: positive;
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 14 November.
- During a meeting of the Scientific Advisory Group (SAG) for CNS on 11 January 2006 experts were convened to address questions raised by the CHMP.
- During the CHMP meeting on 23-26 January 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.

- The Rapporteurs circulated the Day 180 Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 31 March. On 19 April an amendment to the clinical Assessment Report was circulated with an updated respond to question 4.
- During the CHMP meeting on 24-27 April 2006, outstanding issues were addressed by the applicant during an oral explanation before the CHMP.
- During the meeting on 24-27 April 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 Tysabri on 27 April 2006. The applicant provided the letters of undertaking on the follow-up measures to be fulfilled post-authorisation and on the proposed observational cohort study on 27 April 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 27 June 2006.