BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Roche Registration Limited submitted on 26 August 2004 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Tarceva through the centralised procedure. After agreement by the CHMP on 22-23 June 2004 this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.
The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:

Rapporteur	Dr. Ersbøll	Co-Rapporteur	Dr. Lekkerkerker

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.

2 Steps taken for the assessment of the product

- The application was received by the EMEA on 26 August 2004.
- The procedure started on 20 September 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 30 November 2004 . The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 1 December 2004 .
- During the meeting on 17-20 January 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 20 January 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 10 March 2005.
- The summary report of the inspection carried out at the manufacturing site Schwarz Pharma Manufacturing Inc between 14-18 March 2005 was issued on 27 April 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 26 April 2005.
- During the CHMP meeting on 23-26 May 2005, the CHMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant, and questions for the CHMP Scientific Advisory Group (SAG) for Oncology.
- The applicant submitted the full written responses to the CHMP List of Outstanding Issues and questions for the CHMP Scientific Advisory Group (SAG) for Oncology on 06 June 2005
- A meeting of the SAG for Oncology took place at the EMEA on 09 June 2005 to discuss the questions related to Tarceva. During this meeting the applicant presented the applicant’s views on the questions related to Tarceva. Answers and comments were given by the group.
- The Rapporteurs circulated an updated Joint Assessment Report on the applicant’s responses to the List of Outstanding Issues to all CHMP members on 17 June 2005.
- During the meeting on 20-23 June 2005, 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 Tarceva on 23 June 2005. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 21 June 2005.
- The CHMP opinion was forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 19 September 2005.