BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Roche Registration Limited submitted on 4 December 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Avastin, in accordance with the centralised procedure falling within the scope of Part A 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 were:
Rapporteur: Jens Ersbøll Co-Rapporteur: Eva Skovlund

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 4 December 2003.
- The procedure started on 22 December 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 4 March 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 2 March 2004.
- During the meeting on 20-22 April 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 22 April 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 4 June 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 16 August 2004.
- During the CHMP meeting on 14-16 September 2004, 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 preliminary responses to the CHMP List of Outstanding Issues in preparation of the SAG for Oncology on 5 October 2004.
- A meeting of the SAG for Oncology took place at the EMEA on 13 October 2004 to discuss the questions related to Avastin. During this meeting the applicant presented the applicant's views on the questions related to Avastin. Answers and comments were given by the group.
- The applicant submitted the full written responses to the CHMP List of Outstanding Issues on 14 October 2004.
- The Rapporteurs circulated an updated Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 15 October 2004.
- During the meeting on 18-21 October 2004, 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 Avastin on 21 October 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 20 October 2004.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 12 January 2005.