BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant SmithKline Beecham plc submitted on 27 May 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Avaglim, 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, (i.e. complete dossier with administrative, quality, non-clinical and clinical data)

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

Licensing status:
At positive opinion, Avaglim has been given a Marketing Authorisation in Canada on 21 October 2004 and the United States of America 29th November 2005. A new application has been filed in the following countries: Chile, Columbia, Philippines, South Africa, South Korea and Switzerland.

The Rapporteur and Co-Rapporteur appointed by the CHMP were

Rapporteur Dr. J.F.F. Lekkerkerker Co-Rapporteur Dr. P. Neels

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 27 May 2005.
- The procedure started on 15 June 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 26 August 2005 . The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 7 September 2005 .
- During the meeting on 10-13 October 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 13 October 2005).
- The applicant submitted the responses to the CHMP consolidated List of Questions on 13 January 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 27 February 2006 .
- During the CHMP meeting on 20-23 March 2006 the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP consolidated List of outstanding issues on 28 March 2006
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding issues to all CHMP members on 11 April 2006.
- 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 Avaglim on 27 April 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 24 April 2006. The European Commission granted a marketing authorisation valid throughout the European Union for Avaglim on 27 June 2006.