BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Limited submitted on 8 February 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Lucentis, through the centralised procedure falling within the Article 3(1) and point 1 of Annex of Regulation (EC) No 726/2004.

The legal basis for this application refers to:

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

The application submitted is a complete dossier: composed of administrative information, complete quality data, non-clinical and clinical data based on applicants' own tests and studies and/or bibliographic literature substituting/supporting certain tests or studies.

Scientific Advice:
The applicant received Scientific Advice from the CHMP on 21 November 2003. The Scientific Advice pertained to clinical aspects of the dossier.

Licensing status:
A new application was filed in the following country: USA.
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 were:
Rapporteur: Bengt Ljungberg Co-Rapporteur: Gonzalo Calvo Rojas

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 8 February 2006.
- The procedure started on 1 March 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 18 May 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 23 May 2006.
- During the meeting on 26-29 June 2006, 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 29 June 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 7 August 2006.
- The summary report of the inspection carried out at the following site Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080-4990, USA between 8 and 15 May 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 22 September 2006.
- During the CHMP meeting on 16-18 October 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 2 November 2006.
- During the meeting on 13-16 November, 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 Lucentis on 16 November 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 15 November 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 22 January 2007.