1 BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Pfizer Limited submitted on 31 August 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Macugen, through the centralised procedure. The eligibility to the centralised procedure by the CHMP was agreed upon on 25 March 2004.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:
Rapporteur: Bruno Flamion Co-Rapporteur: Bengt Ljungberg

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

Licensing status:

A new application is approved in the following countries: USA and Canada.

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 31 August 2004.
- The procedure started on 20 September 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 6 December 2004.The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 29 November 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 15 April 2005.
- The summary report of the inspection carried out at the manufacturing Raylo Fine Chemicals site was signed by inspectors on 19 May 2005, and for the manufacturing Gilead Pharmaceuticals site was signed by the inspectors on 18 March 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 31 May 2005
- During the CHMP meeting on 20-23 June 2005, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant
- A clarification meeting with the Rapporteur and Co-Rapporteur on the CHMP list of outstanding issues was held on 22 June 2005.
- The applicant submitted the responses to the CHMP list of outstanding issues on 8 August 2005.
- The Rapporteurs circulated the updated Joint Assessment Report on the applicant's responses to the List of Outstanding Issues on 1 September 2005
- During the meeting on 12-15 September 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 Macugen on 15 September 2005. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 14 September 2005.
- On 28 November 2005 the EMEA reviewed spontaneous cases of anaphylactic events-hypersensitivity notified for Macugen and in consultation with the rapporteur requested the applicant to provide a review of preclinical data, of all reported cases of anaphylactic events/hypersensitivity, and of relevant published literature, and to propose any measures necessary to address any safety concerns.
- On 2 December 2005 the applicant submitted a review document together with supportive data. On 5 December 2005 the applicant submitted a proposal to revise the Annexes of the CHMP opinion of 15 September 2005.

- The Rapporteur's Preliminary Assessment Report was circulated to the CHMP on 6 December 2005.
- On 6 December 2005 the EMEA informed the European Commission about the need for CHMP to assess new safety information for Macugen during the CHMP meeting of 12-15 December 2005.
- On 8 December 2005, the European Commission informed the EMEA that the preparation of a Commission decision on the basis of the CHMP opinion of 15 September 2005 had been suspended, and that the dossier had been referred back to the EMEA for further consideration during the CHMP meeting of 12-15 December 2005.
- The Rapporteur's Updated Assessment Report was circulated to the CHMP on 9 December 2005.
- During the meeting on 12-14 December 2005, in the light of the information submitted and the proposed revisions of the Summary of Product Characteristics and Package Leaflet, the CHMP adopted a revised opinion for granting a Marketing Authorisation for Macugen on 14 December 2005.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 31 January 2006.