BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Aventis/Pfizer EEIG submitted on 5 February 2004 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Exubera, 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.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:
Rapporteur: Dr. Gottfried Kreutz Co-Rapporteur: Dr. Pieter Neels

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 5 February 2004.
- The procedure started on 23 February 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 7 May 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 16 May 2004.
- During the meeting on 22-23 June 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 25 June 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 21 October 2004.
- The summary report of the inspection carried out at the manufacturing site Nektar Therapeutics, San Carlos, USA and Pfizer Inc., Terre Haute, USA between 15-17 and 20-22 September 2004 was issued on 8 November 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 20 January 2005 and 24 January 2005.
- During the CHMP meeting on 17 February 2005, 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 list of outstanding issues to be addressed in writing on 13 May 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the list of outstanding issues on 3 June 2005.
- During the QWP meeting on 07-09 June 2005, outstanding quality issues were addressed by the applicant during an oral clarification before the QWP.
- During the Ad-hoc Expert Group meeting on 15 June 2005, clinical safety concerns were discussed with external experts.
- During the CHMP meeting on 21-23 June 2005, outstanding issues were addressed by the applicant during an oral explanation before the CHMP.
- During the CHMP meeting on 21-23 June 2005, the CHMP agreed on a list of remaining outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP list of remaining outstanding issues to be addressed in writing on 14 September 2005.
- During the Ad-hoc Expert Risk Management Plan meeting on 28 September 2005, safety concerns addressed in the risk management plan were discussed with external experts.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the list of remaining outstanding issues dated 28 September 2005.
- During the meeting on 11-13 October 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 Exubera on 13 October 2005. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 13 October 2005.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 24 January 2006.