BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Pfizer Limited submitted on 7 December 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for CELSENTRI, through the centralised procedure falling within the Article 3(1) and point 3 of Annex of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 27 July 2006.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, 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 test(s) or study(ies).

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

Licensing status:
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: B. Ljungberg
Co-Rapporteur: B. Silva Lima
CHMP Peer reviewer: E. Abadie

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 7 December 2006.
- The request for Accelerated Assessment was accepted by the CHMP on 14 December 2006 subject to review at time of discussion of the List of Questions.
- The procedure started on 27 December 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 16 March 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 27 March 2007.
- During the meeting on 23-26 April 2007, 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 27 April 2007.
- The Accelerated Assessment was reviewed considering the consolidated List of Questions and during the meeting on 23-26 April 2007 the CHMP decided to continue to assessment under "normal" centralised timetable.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 22 May 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 5 June 2007.
- The CHMP agreed on a list of outstanding issues to be addressed by the applicant in an oral explanation via written procedure on 14 June 2007. The final list of outstanding issues was sent to the applicant on 15 June 2007.
- During the CHMP meeting on 18-21 June 2007, the applicant gave an oral explanation in front of the CHMP. Furthermore, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant including a list of questions to be addressed by the SAG HIV/Viral Diseases. The final List of outstanding Issues as well as the list of questions to be addressed in front of the SAG was sent to the applicant on 21 June 2007.

- The applicant submitted the responses to the CHMP List of outstanding Issues on 27 June 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding Issues to all CHMP members on 9 July 2007.
- During a meeting of the SAG-HIV/Viral Diseases on 10 July 2007, experts were convened to address questions raised by the CHMP. The applicant gave an Oral Explanation during this meeting. A report of this meeting was forwarded to the CHMP.
- During the meeting on 16-19 July 2007, 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 CELSENTRI on 19 July 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 18 July 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 18 September 2007.