BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Otsuka Pharmaceutical Europe Ltd submitted on 5 December 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Abilify, through the centralised procedure. After agreement by the CPMP on 28 June 2001, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Prof C. Sampaio Co-Rapporteur: Pharm. M. Avgerinos

Scientific Advice:

The applicant did not seek scientific advice at the CPMP.

Licensing status:

Abilify has been given a Marketing Authorisation in Mexico on 17 July 2002, in Brazil on 11 April 2003, in the USA on 15 November 2002, in Puerto Rico on 25 November 2002, in Australia on 21 May 2003 and in Peru on 20 May 2003.

A new application was filed in the following countries: Switzerland, Turkey, Japan and Malaysia.

2. Steps taken for the assessment of the product

- The procedure started on 24 December 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 13 March 2002 . The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 4 March 2002
- During the meeting on 23-25 April 2002, the CPMP 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 April 2002
- GCP inspections were carried out at two sites, one in Bulgaria on 19-21 June 2002 and the other in Estonia on 26-28 June 2002. (Study 31-98-304-01).
- The applicant submitted the responses to the CPMP consolidated List of Questions on 3 September 2002.
- The Rapporteur's circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 28 October 2002.
- During the CPMP meeting on 19-21 November 2002, the CPMP agreed on a List of Outstanding Issues to be addressed in writing and/or in an oral explanation by the applicant.
- During the CPMP meeting on 18-20 February 2003, outstanding issues were addressed by the applicant during an oral explanation before the CPMP.
- Follow up GCP inspections were carried out in Poland on 4-6 March 2003, in France on 19-21 March 2003, and at three sites in Russia on 28 and 31 March 2003, 1-2 April 2003 and 3-4 April 2003. (Study 31-98-304-01).
- The applicant submitted the responses to the CPMP List of Outstanding Issues on 16 June 2003.
- The Rapporteur circulated the Assessment Report on the applicant's responses to the List of Outstanding Issues to all CPMP members on 17 July 2003.
- During the CPMP meeting on 22-24 July 2003, the CPMP agreed on a 2nd List of Outstanding Issues to be addressed in writing and/or in an oral explanation by the applicant.

- The applicant submitted the responses to the 2nd CPMP List of Outstanding Issues on 27 October 2003.
- The Rapporteur circulated the Assessment Report on the applicant's responses to the 2nd List of Outstanding Issues to all CPMP members on 12 November 2003.
- During the CPMP meeting on 18-20 November 2003, outstanding issues were addressed by the applicant during an oral explanation before the CPMP.
- A GMP inspection for the clinical trial batch records (Study 31-98-304-01) was carried out at the CRO on 7-9 January 2004.
- During the meeting on 24-26 February 2004, the CPMP, 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 Abilify on 26 February 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 24 February 2004.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 4 June 2004.