BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company, Pharmacia and Upjohn Ltd submitted on 5 October 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for DepoCyte, through the centralised procedure. After agreement by the CPMP on 24 September 1997, confirmed on 20 May 1999, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended. On 25 July 2000, the EMEA was notified that following the merger of Pharmacia and Upjohn Ltd with Monsanto-Searle, and the consequent loss of marketing rights to the medicinal product, the applicant changed to Skye-Pharma Plc.

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

Rapporteur:	Dr. D. Jefferys (until March 2000) Dr. F. Rotblat
Co-Rapporteur:	R. Gaspar (until January 2000) Prof. J. Guimarães Morais (until January 2001) Prof. B. Silva Lima

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 procedure started on 22 October 1999.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 29 December 1999. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 6 January 2000.
- During the meeting on 15-17 February 2000 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 17 February 2000.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 8 September 2000.
- The summary report of the inspection carried out at the manufacturing site between 12 and 14 September 2000 of the manufacturer of the bulk product was issued on 9 October 2000 and an addendum to this report was issued on 21 March 2001.
- The Rapporteur circulated the response assessment report on the applicant’s responses to the List of Questions to all CPMP members on 26 October 2000.
- During the CPMP meeting on 14-16 November 2000 a List of Outstanding Issues was adopted by the CPMP.
- The applicant submitted the responses to the CPMP consolidated List of Outstanding Issues on 17 January 2001.
- The Rapporteur circulated the response assessment report on the applicant’s responses to the List of Outstanding Issues to all CPMP members on 16 February 2001.
- During the March 2001 CPMP meeting, the remaining outstanding issues were addressed by the applicant during an oral explanation before the CPMP on 27 February 2001
- During the March 2001 meeting 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 DepoCyte on 29 March 2001.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 11 July 2001.