BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Schwarz Pharma Ltd. submitted on 29 September 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Neupro, through the centralised procedure.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application, (i.e. complete dossier with administrative, quality, non-clinical and clinical data).

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:

Rapporteur:	C. Sampaio	Co-Rapporteur	B. van Zwieten-Boot

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 29 September 2004.
- The procedure started on 18 October 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 10 January 2005 and on 18 January 2005 . The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 7 January 2005 and on 10 January 2005).
- During the meeting in February 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 18 February 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 2 August 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 21 September 2005 .
- During the CHMP meeting in October 2005, the CHMP agreed on a List of Outstanding Issues to be addressed in writing and in an oral explanation by the applicant.
- The applicant submitted the responses to the CHMP List of Outstanding Issues on 25 October 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CHMP members on 9 November 2005.
- During the CHMP meeting in November 2005, outstanding issues were addressed by the applicant during an oral explanation before the CHMP and 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 on 24 November 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CHMP members on 7 December 2005.
- During the meeting in December 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 Neupro on 15 December 2005. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 9 December 2005.