BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Nycomed Imaging AS submitted on 26 October 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for NeoSpect, through the centralised procedure. After agreement by the CPMP on 27 July 2000, 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: Dr Mary Teeling Co-Rapporteur: Dr Jens Ersbøll

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 20 November 1998
- The Rapporteur's first assessment report was circulated to all CPMP Members on 29 January 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 29 January 1999
- During the meeting on 23 – 25 March 1999, 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 March 1999 (Annex 3).
- The Applicant submitted the responses to the CPMP consolidated List of Questions on 22 September 1999
- The summary report of the inspection carried out at the manufacturing site on 27 January 2000 was issued on 3 February 2000 (Annex 4).
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 23 November 1999 (Annex 5).
- During the CPMP meeting on 14 – 16 December 1999, outstanding issues were addressed by the applicant during a hearing before the CPMP. A 6 month clock stop was agreed to allow the Applicant to finalise a clinical study.
- The CPMP Consolidated Assessment Report and List of Outstanding Issues (dated 16 December 1999) was sent to the Applicant on 17 December 1999.
- The Applicant submitted the responses to the CPMP Consolidated Assessment Report and List of Outstanding Issues on 19 June 2000.
- During the meeting on 25 – 27 July 2000 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion (majority) for granting a Marketing Authorisation to NeoSpect on 27 July 2000.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 29 November 2000.