I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Abbott Laboratories Ltd, UK, submitted on 31 July 1998, an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA), for Synagis, in accordance with the centralised Procedure for the medicinal product Synagis (palivizumab) falling within the scope of Part A of the Annex to Council Regulation No (EC) 2309/93.

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

Rapporteur: Dr. G. Jensen Co-Rapporteur: Dr. Haase (Dr. Schaeffner)

Licensing status:

2. Synagis has been given a Marketing Authorisation in United States on 19 June 1998.

3. 2. Steps taken for the assessment of the product

- The Rapporteur's initial assessment report was circulated to all members of the CPMP on 2 November 1998.
- The Co-rapporteur's initial assessment report was circulated to the members of the CPMP on 2 November 1998.
- The BWP during its meeting on 9 December 1998 prepared a recommendation to the CPMP on quality aspects of the assessment report.
- The CPMP during its meeting on 15-17 December 1998 finalised the list of questions to be addressed by the company.
- The CPMP consolidated list of questions was sent to the company on 17 December 1998 (Stop of the clock).
- The CPMP requested an inspection of the manufacturing site of Boehringer Ingelheim Pharma KG on the basis of the need to assess GMP compliance. The inspection took place on 8-10 March 1999. The inspection report was forwarded to EMEA on 22 April 1998. The general impression of the Quality Assurance System and compliance with the EU GMP rules is positive.
- The applicant submitted the responses to the consolidated CPMP list of questions on 26 February 1999 and the clock restarted.
- The Rapporteur/Co-Rapporteur joint assessment report on the applicant's responses and joint recommendation was circulated to CPMP members on 31 March 1999.
- The CPMP during its meeting on 21 April 1999 discussed the joint assessment report and decided to stop the clock for an oral presentation on clinical issues in May. A list of outstanding clinical and quality issues was adopted by the CPMP .
- The applicant submitted responses to the quality outstanding points on 30 April 1999.
- The Rapporteur's/Co-rapporteur's joint assessment report on the responses to the quality questions was circulated on 6 May 1999.
- The BWP during their meeting on 11 May 1999 prepared a recommendation to the CPMP on the outstanding quality aspects with particular reference to virus validation issues .
- Oral explanations were given by the Applicant on 18 May 1999.
- Undertaking signed by the Company on the follow-up measures on 19 May 1999.

- During the meeting on 17-19 May 1999 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 Synagis on 19 May 1999.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 13 August 1999.