BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Novo Nordisk A/S Denmark submitted an application to all EU Member States for NovoSeven, through the Concertation Procedure No. 74 on March 1994. In application to article 2 of Directive 93/41/EEC on 5 January the company Novo Nordisk A/S Denmark transferred to the European Agency for the Evaluation of Medicinal Products (EMEA), into the new centralised procedure, the application for Marketing Authorisation for NovoSeven, falling within the scope of Part A of the Annex to Council Regulation (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr. W. F. van der Giesen Co-Rapporteur: Dr. D. Jefferys

Licensing status:
NovoSeven has been given Marketing Authorisations in the following countries

Australia	Kuwait
Bahrain	Lithuania
Brazil	Malta
Bulgaria	New Zealand
Canada	Norway
Costa Rica	Poland
Croatia	Romania
Cyprus	Singapore
Czech Republic	Slovakia
EU	Slovenia
Federal Republic of Yugoslavia	South Africa
Hong Kong	South Korea
Hungary	Switzerland
Israel	Taiwan
Japan	Thailand
Jordan	USA

2. Steps taken for the assessment of the product

- The Rapporteur's initial assessment report on the toxico-pharmacological data was prepared 9 May 1994.
- The Rapporteur's initial chemical-pharmaceutical assessment report was prepared on 14 May 1994.
- The Rapporteur's clinical assessment report was prepared 16 May 1994.
- The Rapporteur's initial assessment reports were circulated to all the members of the previous CPMP on the 6th of June 1994.
- The Co-rapporteur's initial assessment report (23 March 1994) was circulated to all the members of the CPMP on the 26 July 1994.
- The CPMP consolidated list of comments was sent to the applicant Novo Nordisk A/S DK on 17 August 1994.
- The applicant submitted the responses to the first consolidated CPMP list of comments on 4 November 1994.
- The Rapporteur's first "responses" pharmacological-toxicological assessment report was prepared on 30 November 1994.

- The applicant submitted the responses to the clinical questions of the first consolidated CPMP list of comments on 16 January 1995.
- The Rapporteur's first "responses" chemical-pharmaceutical assessment report was prepared on 24 January 1995.
- A meeting took place between the Rapporteur, Co-Rapporteur and applicant to discuss remaining biotechnological issues on 28 February 1995.
- The Rapporteur's first "responses" clinical assessment report was prepared on 3 March 1995.
- The Rapporteur's first "responses" chemical-pharmaceutical assessment report was circulated with a proposal for a second consolidated list of comments on 9 March 1995.
- The Co-Rapporteur circulated the first "responses" assessment reports to all members on 20 March 1995.
- The applicant' s answers to the biotechnology/biological questions were considered by the CPMP ad hoc Biotechnology Working Party during its meeting on 3-4 April 1995.
- The CPMP in its meeting on 26-27 April 1995 discussed the recommendations presented by the CPMP ad hoc Biotechnology W.P.
- The remaining comments were sent to the applicant on 3 May 1995.
- The applicant submitted their responses to the second consolidated CPMP list of questions on 9 June 1995.
- The Rapporteur's second "responses" pharmacological-toxicological assessment report was prepared on the 25 July 1995.
- The Rapporteur's second "responses" chemical-pharmaceutical assessment report was prepared on 18 August 1995.
- The Rapporteur's second "responses" clinical assessment report was prepared on 21 August 1995.
- The Rapporteur's second "responses" assessment reports were circulated to all the CPMP members on the 22 August 1995.
- During the CPMP ad hoc Biotechnology W.P. meeting on 7-8 September 1995, the assessment reports circulated by the Rapporteur and the further information provided by the applicant were discussed.
- During the CPMP meeting on 13 September 1995, the recommendation of the Biotechnology W.P. was discussed and a hearing with the applicant was planned in order to address remaining concerns related to the viral safety of bovine serum used for production of NovoSeven.
- During the CPMP Biotechnology W.P. meeting on 16 October 1995, the clarifications given by the company were considered. The Biotech WP party recognised the clinical usefulness of this medicinal product and considered that the Company had made considerable efforts to assure the viral safety of the final product.
- The CPMP in their meeting on 17-18 October considered the report from the Biotechnology Working Party and general agreement was reached that the clarifications given by the company were reassuring, and that the finished product had a satisfactory viral safety profile due to the quality system put into place by the company.
- The company submitted on 17 October 1995 their letter of commitment for providing information on the remaining biotechnology/pharmaceutical points as requested by the Rapporteur.
- The CPMP in the light of the current scientific standards issued on 18.10.1995 three positive opinions for granting a marketing authorisation to three different presentations (strengths) of NovoSeven.