BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company TKT Europe AB submitted on 4 July 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Replagal, in accordance with the centralised procedure falling within the scope of Part A 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. Hans van Bronswijk Co-Rapporteur: Dr. Per Nilsson

Scientific Advice:
The applicant received Scientific Advice from CPMP on 24 May 1999. The Scientific Advice pertained to parts II, III and IV of the dossier.

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 18 July 2000.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 27 September 2000. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 26 September 2000.
- During the meeting on 14-16 November 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 16 November 2000.
- The company submitted the responses to the CPMP consolidated list of questions on 24 November 2000.
- The summary report of the inspection carried out at the manufacturing sites between 28 November 2000 and 1 December 2000 and on 17 January 2001 was issued on 29 January 2001.
- The Rapporteur circulated the response assessment report on the company’s responses to the list of questions to all CPMP Members on 4 January 2001 Part III and IV, 10 January 2001 Part I and II.
- During the meeting on 23-25 January 2001, the CPMP agreed on a list of outstanding issues to be addressed by the applicant in writing and if necessary during an oral explanation. The list of outstanding issues was sent to the applicant on 25 January 2001. A final revised list of outstanding issues was sent to the applicant on 2 February 2001.
- The applicant provided written information on these outstanding issues to all CPMP members on 5 February 2001. The joint Rapporteur/Co-rapporteur assessment report on the written responses to the list of outstanding issues was circulated to all CPMP members on 12 February 2001.
- During the CPMP meeting on 28 February 2001, outstanding quality and clinical issues were addressed by the applicant during an oral explanation before the CPMP.

- During the meeting on 27 - 29 March 2001 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 Replagal 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 3 August 2001.