BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Nycomed Austria GmbH submitted on 4 July 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for TachoSil, in accordance with the centralised procedure falling within the scope of Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993, as amended.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:
Rapporteur: Dr. Manfred Haase Co-Rapporteur: Dr. Ian Hudson

2. Steps taken for the assessment of the product

- The procedure started on 22 July 2002.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 30 September 2002 . The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 10 September 2002.
- During the meeting on 19 November 2002, 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 21 November 2002.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 14 October 2003.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 24 November 2003.
- During the CPMP meeting on 18 December 2003, the CPMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CPMP members on 3 February 2004.
- During the meeting on 24-26 February 2004, 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 TachoSil on 26 February 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 26 February 2004.