BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Abbott Laboratories Ltd submitted on 28 March 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Trudexa, 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 Tomas Salmonson Co-Rapporteur: Dr Pasqualino Rossi

Scientific Advice:

The applicant received Scientific Advice from the CPMP on 29 July 1999 and 19 October 2000. The Scientific Advice pertained to parts II, III and IV of the dossier.

Licensing status:

Trudexa has been given a Marketing Authorisation in the USA on 31 December 2002.

2. Steps taken for the assessment of the product

- The procedure started on 22 April 2002.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 3 July 2002. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 3 July 2002
- During the meeting on 23 –25 July 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 25 July 2002.
- The company submitted the responses to the CPMP consolidated List of Questions on 12 November 2002.
- The Rapporteur and Co-Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 3 January 2003).
- The summary report of the inspection carried out at the manufacturing site between 18 and 22 November 2002 of the Abbott Bioresearch Center was issued on 15 January 2003.
- During the CPMP meeting on 21-23 January 2003, the CPMP agreed on the List of Outstanding Issues to be sent to the Applicant.
- The company submitted the responses to the List of Outstanding Issues on 12 March 2003.
- The Rapporteurs circulated the response Joint Assessment Report on the company's responses to the List of Outstanding Issues to all CPMP members on 4 April 2003.
- During the CPMP meeting on 23-25 April 2003, the CPMP agreed on an additional List of Outstanding Issues to be sent to the Applicant.
- The company submitted the responses to the additional List of Outstanding Issues on 2 May 2003.
- The Rapporteurs circulated the response Joint Assessment Report on the company's responses to the additional List of Outstanding Issues to all CPMP members on 9 May 2003.
- The company provided on 22 May 2003, a letter of undertaking on the follow-up measures to be fulfilled as requested by the CPMP.
- During the meeting on 20-22 May 2003 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 Trudexa on 22 May 2003.

- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 1 September 2003