BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Merck Sharp & Dohme Ltd. submitted on 30 October 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for EMEND, through the centralised procedure. After agreement by the CPMP on 25 July 2002, this medicinal product has been referred to 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 Per Nilsson Co-Rapporteur: Dr Barbara van Zwieten-Boot

Scientific Advice:

The applicant did not seek scientific advice from the CPMP.

Licensing status:

The product was authorised in the USA on 26 March 2003.

2. Steps taken for the assessment of the product

- The procedure started on 18 November 2002.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 28 January 2003 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 3 February 2003 (Annex 2).
- During the meeting on 18-19 March 2003 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 19 March 2003 (Annex 3).
- The Applicant submitted the responses to the CPMP consolidated List of Questions on 14 April 2003.
- The Rapporteur and Co-Rapporteur circulated the response Assessment Report on the Applicant's responses to the List of Questions to all CPMP members on 26 May 2003 (Annex 4).
- During the meeting on 24-26 June 2003, the CPMP adopted a list of outstanding issues sent to the Applicant on 26 June 2003 (Annex 5).
- The company submitted the responses to the CPMP consolidated list of outstanding issues on 4 July 2003.
- The Rapporteur and Co-Rapporteur circulated the Assessment Report on the Applicant's responses to the List of Outstanding Issues to all CPMP members on 15 July 2003 (Annex 6).
- During the meeting on 22-24 July 2003, outstanding issues were addressed by the Applicant who gave oral explanations before the CPMP on 23 July 2003.
- During the meeting on 22-24 July 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 EMEND on 24 July 2003.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 12 November 2003.