BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Merck Sharp and Dohme Limited submitted on 6 December 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Invanz (ertapenem), through the centralised procedure. After agreement by the CPMP on 25 September 2000, 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 F. Rotblat Co-Rapporteur: Prof Silva Lima

Scientific Advice:

The applicant did not seek scientific advice from the CPMP.

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 26 December 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 6 March 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 19 March 2001.
- During the meeting on 24-26 April 2001, 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 26 April 2001.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 11 July 2001.
- The Rapporteur circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 17 September 2001.
- During the meeting on 16-18 October 2001, the CPMP agreed on a List of Outstanding Issues to be addressed by the applicant in writing and during an oral explanation. The final List of Outstanding Issues was sent to the applicant on 18 October 2001.
- The applicant provided responses to the List of Outstanding Issues on 22 November 2001.
- The Rapporteur circulated the Assessment Report on the applicant's responses to the pharmaceutical outstanding issues to all CPMP members on 7 December 2001.
- During the CPMP meeting on 11-13 December 2001, outstanding issues were addressed by the applicant during an oral explanation before the CPMP.
- The applicant provided an undertaking letter of the follow-up measures to be fulfilled post-authorisation on 17 January 2002.
- During the meeting on 15-17 January 2002 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion by majority for granting a Marketing Authorisation to Invanz on 17 January 2002.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which issued the corresponding Decision on 18 April 2002.