BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Bristol-Myers Squibb Pharma EEIG submitted on 27 September 1996 an application for Marketing Authorisation to the European Medicines Evaluation Agency (EMEA) through the centralised procedure. After agreement by the CPMP, this medicinal product was referred to Part B of the Annex to Council Regulation EEC No 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CPMP were as follows:

Rapporteur: F. de Andrés-Trelles Co-Rapporteur: C.Strömberg

Licensing status

The product was not licensed in any country outside the EU at the time of submission of the application.

2. Steps taken for the assessment of the product

- An application for marketing authorisation was submitted to the EMEA on 27 September 1996. The centralised procedure started on 21 October 1996.
- The Rapporteur's assessment report was circulated to all CPMP Members on 16 January 1997. The Co-Rapporteur's assessment report was circulated to all CPMP Members on 9 January 1997.
- The Rapporteur's and Co-Rapporteur's assessment reports and the comments from other CPMP Members were discussed during the CPMP meeting in February 1997 and the CPMP consolidated list of questions was adopted on 19 February 1997.
- An inspection of the manufacturing site of the finished medicinal product at Bristol-Myers Squibb Company (2400 West Lloyd Expressway, Evansville, Indiana, 47721-001, United States of America) was carried out by the Inspection Services of France and of the United Kingdom on 17-19 March 1997.
- The responses to the consolidated list of questions were provided on 6 March 1997.
- The joint Rapporteur's and Co-Rapporteur's assessment report on the responses provided by the applicant was sent to all CPMP Members on 9 April 1997.
- Additional information regarding quality issues together with an updated version of the Summary of Product Characteristics, Package Leaflet and Labelling, were provided by the applicant on 30 April 1997.
- Comments from other CPMP Members were received by 5 May 1997, and the Rapporteur circulated on 8 May 1997 a summary addressing outstanding quality, preclinical and clinical issues. An updated version of the Summary of Product Characteristics, Package Leaflet and Labelling, were also included for discussion at the CPMP May meeting.
- During the May CPMP meeting, the final wording regarding the posology to be introduced in the Summary of Product Characteristics was fully discussed and agreed by the CPMP.
- In the light of the overall data submitted and scientific discussion within the Committee, the CPMP issued a positive opinion for granting a Marketing Authorisation to Karvea on 15 May 1997.
- The CPMP opinion was forwarded, in all official languages of the European Union, to the European Commission on 10 June 1997 which adopted the corresponding Decision on 27 August 1997.