

BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Merck KGaA submitted on 1 July 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMA) for Erbitux, 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 Per Nilsson

Co-Rapporteur: Dr Manfred Haase

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 21 July 2003.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 29 September 2003. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 29 September 2003.
- During the 3-5 November 2003 meeting the BWP adopted the BWP report with a recommendation to the CPMP incorporating the draft List of Questions to be adopted at the November 2003 CPMP meeting.
- During the meeting on 18-20 November 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 21 November 2003.
- The company submitted the responses to the consolidated List of Questions on 16 December 2003.
- The Rapporteurs circulated the joint assessment report on the applicant's responses to the List of Questions to all CPMP members on 30 January 2004
- During the CPMP meeting on 24-26 February 2004, the CPMP agreed on a List of Outstanding Issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CPMP's List of Outstanding Issues on 5 March 2004.
- The Rapporteurs circulated the updated joint assessment report on the applicant's responses to the List of Outstanding Issues on 12 March 2004.
- During the meeting on 23-24 March 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 Erbitux on 24 March 2004.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 29 June 2004.