# I BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company Bristol-Myers Squibb Pharma EEIG submitted on 22 November 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Vaniqa, through the centralised procedure. After agreement by the CPMP on 3 August 1999, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CPMP and the initial evaluation teams were:

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| Rapporteur: | Dr. Mary Teeling<br>(until 9 August 2000)<br><br>Dr. Patrick Salmon<br>(from 9 August 2000) | Co-Rapporteur: | Dr. Tomas Salmonson |

**Licensing status:**

A new drug application was filed in the following countries: USA (September 99).

## 2. Steps taken for the assessment of the product

- The procedure started on 3 January 2000.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 25 February 2000. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 25 February 2000.
- During the meeting on 11-12 April 2000 the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 11-12 April 2000.
- The company submitted the responses to the consolidated list of questions on 7 August 2000.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 14 September 2000.
- A List of outstanding issues was adopted at the CPMP meeting on 17-19 October 2000.
- The applicant provided supplementary information on 27 October 2000.
- During the meeting on 12-14 December 2000 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 Vaniqa on 14 December 2000.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 March 2001.