BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Ltd submitted on 1 March 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Glivec, which was designated as an orphan medicinal product EU/3/01/021 on 14 February 2001, through the centralised procedure. After agreement by the CPMP on 27 July 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. Alonso Co-Rapporteur: Dr E. Abadie

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 27 March 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 12 June 2001 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 5 June 2001.
- During the CPMP meeting on 26-28 June 2001, the CPMP agreed to an expedited review of the application in view of the quality of the dossier and the outstanding activity of the medicinal product.
- During the meeting on 24 July 2001 the CPMP agreed on the consolidated List of Outstanding Issues to be sent to the applicant. The final List of Outstanding Issues was sent to the applicant on 25 July 2001.
- During the CPMP meeting on 24-26 July 2001, outstanding issues were addressed by the applicant during a hearing before the CPMP.
- During the meeting on 24-26 July 2001 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 Glivec on 26 July 2001. The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 11 November 2001.