BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Boehringer-Ingelheim International GmbH, Germany submitted 3 October 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Beromun, through the centralised procedure. After agreement by the CPMP on 20-23 October 1997, this medicinal product is referred to Part A of the Annex to Council Regulation No. (EC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:

Rapporteur: Dr. Gorm Jensen Co-Rapporteur: Dr. Per Sjöberg

Licensing status:

Beromun does not at present have a marketing authorisation anywhere else in the world. Marketing Authorisation Applications have been submitted in New Zealand (November 1997), Switzerland (December 1997) and South Africa (February 1998).

2. Steps taken for the assessment of the product

- The procedure started on 24 October 1997.
- During its meeting on November 1997, the CPMP agreed that a GMP inspection of the manufacturing site was not necessary.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 7 January 1998 (part II), and 21 January 1998 (parts III/IV)
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 30 December 1997.
- During its meeting on 23-25 February 1998, 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 25 February 1998.
- The company submitted the responses to the consolidated list of questions on 18 August 1998.
- The Rapporteur and the Co-Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP Members on 21 October 1998.
- The applicant submitted on 12 November 1998 responses to the outstanding pharmaceutical questions.
- Rapporteur and Co-Rapporteur joint assessment report was circulated to all CPMP members on 13 November 1998.
- An oral explanation was held at the CPMP meeting on 17 November 1998, to address the remaining outstanding issue of the comparative survival of Beromun/melphalan-ILP treated patients versus patients treated by standard therapy (i.e. amputation or debilitating surgery).
- The CPMP, during their meeting on 17-19 November 1998, considered the responses provided by the company and discussed the recommendations presented by the Rapporteur. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet texts.
- The applicant provided a letter (dated 18 November 1998) of undertaking on the follow-up measures to be fulfilled as requested by the CPMP.
- During the meeting on 17-19 November 1998 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 for Beromun on 19 November 1998**.**