BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company SmithKline Beecham plc submitted on 5 January 1996 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA), for the medicinal product Hycamtin powder for solution for infusion, through the centralised procedure. After agreement by the CPMP on 13 September 1995, this medicinal product is referred to List B in the Annex of the Council Regulation EEC No 2309/93, as it contains a new active substance.

The Rapporteur and Co-Rapporteur appointed by the CPMP, were

Rapporteur: Dr. P. Sjöberg Co-Rapporteur: Dr. E. Alhava

Licensing status:

Hycamtin has been given a Marketing Authorisation in the U.S.A. on 28 May 1996.

A new drug application was filed in the following countries: Australia, Canada, Croatia, Iceland, New Zealand, Norway, South Africa, Switzerland and Venezuela.

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 applicant submitted to the EMEA on 5 January 1996 an application for Hycamtin powder for solution for infusion. The procedure started on 16 January 1996.
- During the February 1996 CPMP meeting, an inspection of the Finished Product Manufacturing Site in the USA was agreed upon to be carried out by the British and Swedish Inspectorates.
- The Co-Rapporteur's initial assessment report was circulated to all CPMP Members on 8 March 1996. The Rapporteur's initial assessment report was circulated to all CPMP Members on 11 March 1996.
- During the meeting on 21 May 1996 the CPMP agreed the consolidated list of questions to be sent to the company.
- The final consolidated list of questions was sent to the company on 22 May 1996.
- The company submitted the responses to the consolidated list of questions on 3 June 1996.
- The Rapporteur and Co-Rapporteur circulated the comments on the company's responses to the list of questions to all CPMP Members on 17 June 1996.
- The Rapporteur and Co-Rapporteur circulated amendments to the assessment of the responses of quality related issues dated 17 June 1996 to all CPMP Members on 16 July 1996.
- The company provided additional information on 16 July 1996, which addressed two clinical issues (the high initial death rate in the topotecan arm of the paclitaxel comparative trial 039 and a justification of a Marketing Authorisation in light of the significant toxicity). This resulted in amendments of the SPC, the package leaflet and the labelling.
- The company submitted a letter of obligations on 16 July 1996, where they agree to provide additional information concerning chemical, pharmaceutical and biological aspects.
- The CPMP during their meeting on 16-17 July 1996, on the basis of the acceptable benefit-risk assessment, issued a positive Opinion for granting a Marketing Authorisation to Hycamtin powder for solution for infusion on 17 July 1996. The CPMP Opinion was forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 12 November 1996.