BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Liposome Technology Inc. submitted an application to all EU Member States for Caelyx through the Concertation Procedure (No. 89) on 21 December 1994. In application of Article 2 of Directive 93/41/EEC, on 19 January 1995, the company Liposome Technology Inc. transferred to the European Agency for the Evaluation of Medicinal Products (EMEA) into the new Centralised Procedure the application for a Marketing Authorisation for Caelyx, falling within the scope of Part B, indent 2 of the Annex to Council Regulation (EEC) 2309/93.

Medicinal products containing the active substance, doxorubicin hydrochloride, have already received in the EU an authorisation for marketing in various indications. The application was, therefore, made under Article 4.8.(a) (iii) of the EEC Directive 65/65.

The Rapporteur appointed by the CHMP was:

Rapporteur: Dr. D. Jefferys

Licensing status:
Caelyx has received (November 1995) in the United States a Marketing Authorisation for the following indication: Treatment of AIDS-related Kaposi's sarcoma in patients with disease that has progressed on prior combination chemotherapy or in patients who are intolerant to such therapy.

2. Steps taken for the assessment of the product

- The Rapporteur's initial assessment report was circulated to all CPMP Members on 13 March 1995.
- The Rapporteur circulated an updated pharmaceutical assessment report on 30 March 1995.
- The consolidated list of questions was sent to the applicant on 31 May 1995.
- A list of additional questions was sent to the applicant on 13 June 1995.
- On 23 August 1995 the applicant notified the EMEA of a change of name from Liposome Technology Inc. to Sequus Pharmaceuticals Inc.
- The applicant submitted its responses to the consolidated list of questions on 7 November 1995.
- The Rapporteur circulated the comments on the applicant's responses to the consolidated list of questions to all CPMP Members on 1 December 1995.
- A preliminary analysis report from a randomised comparison of Caelyx versus bleomycin and vincristine in the treatment of AIDS-related Kaposi's Sarcoma was circulated to all CPMP Members on 31 January 1996.
- The company submitted on 13 February 1996 their letter of commitment for providing final reports for two ongoing clinical trials.
- 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 Caelyx on 15 February 1996. The CPMP Opinion was forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 21 June 1996.