I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Gilead Sciences Limited, UK submitted to the EMEA on 28 December 1995 an application for Marketing Authorisation for Vistide through the centralised procedure. After agreement by the CPMP in July 1995 this medicinal product is referred to List B in the Annex of the Council Regulation EEC No 2309/93, indent 7 as it contains a new active substance.

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

Rapporteur: Prof. J.A. Guimarães Morais Co-Rapporteur: Dr D. Jefferys

Licensing status:

Vistide has been approved in the United States of America on 26 June 1996.

2. Steps taken for the assessment of the product

- An application for Marketing Authorisation for Vistide was submitted to the EMEA on 28 December 1995. The centralised procedure started on 16 January 1996.
- The Rapporteur's assessment report was circulated to all CPMP members on 15 April 1996.
- The Co-Rapporteur's assessment report was circulated to all CPMP members on 15 April 1996.
- The Rapporteur's and Co-Rapporteur's assessment reports and the comments from other CPMP members were discussed during the CPMP meeting in May 1996.
- An inspection for the manufacturing facilities of the finished pharmaceutical dosage form at Ben Venue Laboratories, Bedford, Ohio, United States of America was carried out by the Inspection Service of the United Kingdom on 15 and 16 April 1996.
- The CPMP consolidated List of Questions was adopted on 22 May 1996.
- The responses to the consolidated List of Questions were provided on 27 August 1996.
- The joint Rapporteur's and Co-Rapporteur's assessment report on the responses provided by the applicant was sent to all CPMP members on 21 October 1996.
- A break out session was held during the CPMP in November 1996 in order to discuss the wording of the therapeutic indication.
- The CPMP issued on 18 December 1996 a positive opinion for granting a Marketing Authorisation for Vistide. The CPMP opinion was forwarded, in all official languages of the European Union, to the European Commission which adopted the corresponding Decision on 23 April 1997.

Medicinal product no longer authorised

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