BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Boehringer Mannheim GmbH submitted on 21 April 1995 an application for Marketing Authorisation to the EMEA for Bondronat ampoules, through the centralised procedure, in accordance with Article 6 of Council Regulation (EEC) No. 2309/93. After agreement by the CPMP on 17 May 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: Dr. Gorm Jensen Co-Rapporteur: Dr. Heribert Pittner

Licensing status:

The product was not licensed in any country inside or outside the EEC at the time of submission of the application.

2. Steps taken for the assessment of the product

- The Rapporteur's Assessment Report was circulated to all CPMP Members on 21 July 1995. The Co-Rapporteur's Assessment Report was circulated to all CPMP Members on 11 July 1995.
- During the September CPMP meeting a draft consolidated list of questions was adopted and circulated for comments by 22 September 1995. The final consolidated list of questions was sent to the Company on 28 September 1995.
- The company submitted their responses to the consolidated list of questions on 20 November 1995.
- The Rapporteur circulated the comments on the company's responses to the list of questions to all CPMP Members on 22 December 1995.
- The CPMP during its meeting of 13-15 February 1996, in the light of the current scientific standards, issued a positive Opinion for granting a Marketing Authorisation to Bondronat concentrate for solution for infusion on 14 February 1996.
- On 25 June 1996 the European Commission adopted a favourable Decision on the granting of a Marketing Authorisation for Bondronat.

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