BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Orphan Europe submitted on 22 October 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Phenbut, through the centralised procedure. During the procedure, the name was changed to Ammonaps. After agreement by the CPMP on 17-19 February 1997, this medicinal product is referred to Part B 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. D.Lyons Co-Rapporteur: Dr. J.Yotaki

Licensing status:

US orphan status designation was on 22 November 1993. The product was approved in the USA on 30 April 1996.

2. Steps taken for the assessment of the product

- The procedure started on 30 January 1998.
- During the on 24-25 February 1998, the CPMP rejected the proposed tradename Phenbut.
- During its meeting on 23-25 March 1998, the CPMP agreed on an inspection of the manufacturing facility for the bulk finished product (i.e. Pharmaceutics International Inc., Hunt Valley, USA).
- The Rapporteur's first assessment report was circulated to all CPMP Members on 9 April 1998 (Annex 1). The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 14 April 1998 (Annex 2)
- The summary report of the inspection carried out at the finished product manufacturing site (i.e. Pharmaceutics International Inc., Hunt Valley, USA) between 13-15 May 1998 concluded that the operations are in general compliance with the principles and guidelines of GMP (Annex 3).
- During the meeting on 25-27 May 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 29 May 1998 (Annex 4).
- On 3 August 1998, the applicant proposed a new tradename Ammonaps, which was accepted by the CPMP during its meeting on 20-22 October 1998.
- The company submitted the responses to the CPMP consolidated list of questions on 4 December 1998.
- On 15 January 1999, the Rapporteur circulated to all CPMP Members a scientific overview report on the company's responses to the list of questions, highlighting outstanding Part II and bioequivalence issues. During its meeting on 26-27 January 1999, the CPMP agreed on the second list of outstanding questions to be addressed by the applicant (Annex 5).
- The company submitted the responses to the second list of outstanding questions on 27 April 1999.
- The Rapporteur and the Co-Rapporteur circulated their joint assessment report on the company's responses to all CPMP Members on 30 June 1999 (Annex 6).
- The CPMP, during its meeting on 27- 29 July 1999, discussed the recommendations presented by the Rapporteurs and the amendments to the Summary of Product Characteristics and Package Leaflet texts.

- The Marketing Authorisation Holder, Orphan Europe, provided a letter of undertaking on the specific obligations as requested by the CPMP (on Chemical/pharmaceutical and clinical aspects), dated 29 July 1999 (Annex 7).
- During the meeting on 27-29 July 1999 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 under exceptional circumstances to Ammonaps on 29 July 1999.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 8 December 1999.