BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company H. Lundbeck A/S submitted on 12 October 2001, an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Ebixa, through the centralised procedure. After agreement by the CPMP on 11-12 April 2000, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Prof. Fernando de Andres-Trelles Co-Rapporteur: Prof. Sampaio

Licensing status:

A new drug application was filed in the following countries: Australia

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 procedure started on 22 October 2001
- This application forms part of a multiple application for the product Memantine in the indication "Treatment of patients with moderately severe to severe Alzheimer's disease". The initial application was submitted by Merz + Co. GmbH & Co (EMEA/H/C/378). The review process for both applications has been integrated, allowing the opinion to be adopted in the same timeframe as EMEA/H/C/378 (See Annexes 1-5).
- During the CPMP meeting on 15-17 January 2002, outstanding issues adopted at the November 2001 CPMP meeting, were addressed by the applicant during a hearing before the CPMP.
- During the meeting on 19-21 February 2002 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 to Ebixa on 21 February 2001.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 15 May 2002.