BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Eli Lilly Nederland B.V. submitted on 15 January 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Xigris, in accordance with the centralised procedure falling within the scope of Part A 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: Pharm. G. De Greef Co-Rapporteur: Dr. M. Haase

Licensing status:

Xigris has been given a Marketing Authorisation in US on 21 November 2001:

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 30 January 2001
- The Rapporteur's first assessment report was circulated to all CPMP Members on 19 April 2001 and 23 April 2001. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 28 April 2001
- During the meeting on 29-31 May 2001 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 31 May 2001.
- The company submitted the responses to the consolidated list of questions on 13 July 2001
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 27 and 28 August 2001.
- During the meeting on May 2002 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion under exceptional circumstances for granting a Marketing Authorisation to Xigris for the treatment of adult patients with severe sepsis with multiple organ failure when added to best standard care (for further information see Section 5.1 of SPC) on 30 May 2002. The CPMP Opinion was adopted with additional Specific obligations and Follow up measures that the company agreed to fulfil on an ongoing basis post-opinion.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 22 August 2002.