BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Eli Lilly Nederland B.V. submitted on 26 January 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Liprolog, 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.

This submission concerns an abridged application for Liprolog. The application has been made in accordance with Chapter II Article 4.8 (a) (i) of Council Directive 65/65EEC of 26 January 1995 as amended. The marketing authorisation holder of Humalog, Eli Lilly Nederland B.V., consented to the pharmacological, toxicological and clinical data contained in the original file for Humalog to be used for the purpose of examining this application.

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

Rapporteur: Dr F. Rotblat
Co-Rapporteur: Dr. P. Nilsson

Licensing status:

The corresponding products, under the tradenames Humalog, and Humalog-HumaPen (current tradename Humalog-Pen), Humalog Mix 25, Humalog Mix 25 Pen, Humalog Mix 50 and Humalog Mix 50 Pen, were authorised in the EU through the centralised procedure on 30 April 1996, 16 June 1997 and 19 November 1998.

2. Steps taken for the assessment of the product

- The Rapporteur's first Assessment Report was circulated to all CPMP members on 16 March 2001 (Annex 1)
- During the meeting on 24-26 April 2001 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 Liprolog on 26 April 2001.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 1 August 2001.