BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Boehringer Ingelheim International GmbH submitted on 1 September 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Metalyse, 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: Prof. Bass Co-Rapporteur: Prof. Garattini

Licensing status:

A new drug application was filed in USA in July 1999.

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 24 September 1999.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 3 December 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 2 December 1999.
- During the meeting on 19 January 2000 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 – 20 January 2000.
- The company submitted the responses to the CPMP consolidated list of questions on 3 July 2000.
- The summary report of the inspection carried out at the manufacturing site between 14-19 April 2000 of the Abbott Laboratories, Rocky Mount, USA was issued on 7 June
- The Rapporteur Co-Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 28 August 2000.
- During the meeting on 21 September 2000 the CPMP agreed on the list of outstanding issues to be sent to the company. The final consolidated list of outstanding issues was sent to the company on. 21 September 2000.
- The Joint Rapporteur/Co-Rapporteur Assessment Report on the responses provided by the applicant was circulated to the CPMP on dated 9 and 12 October 2000.
- During the CPMP meeting on 18 October outstanding issues that had previously addressed in writing by the applicant were discussed.
- During the meeting on 18 October 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 Metalyse on 18 October 2000.