BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Boehringer Ingelheim International GmbH and submitted on 6 April 2001 application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for BolusacPlus, through the centralised procedure. After agreement by the CPMP on 23 January 2001, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

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

Rapporteur: Prof. Silvio Garattini Co-Rapporteur: Prof. Rolf Bass

Scientific Advice:

The applicant did not seek scientific advice at the CPMP.

Licensing status:

A new application was filed in the following countries: Republic South Africa and Canada. The product was licensed in the U.S.A. at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 24 April 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 3 July 2001 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 6 July 2001 (Annex 2)
- During the meeting on 26 July 2001 the CPMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 26 July 2001 (Annex 3).
- The company submitted the responses to the CPMP consolidated List of Questions on 8 October 2001
- The Rapporteur and Co-Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 14 November 2001 (Annex 4).
- During the CPMP meeting on 13 December 2001, outstanding issues were addressed by the applicant during a hearing before the CPMP (Annex 5).
- The company submitted the responses to the List of Outstanding Issues on 20 December 2001.
- During the meeting on 15-17 January 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 BolusacPlus on 17 January 2002.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 19 April 2002.