BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Pharmacia Europe EEIG submitted on 12 October 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Dynastat, through the centralised procedure. On 16 October 2001, the EMEA was notified that following the merger of Searle with Pharmacia & Upjohn, the applicant changed to Pharmacia Europe EEIG.

After agreement by the CPMP on 14-16 March 2000, 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: Dr David Lyons Co-Rapporteur: Dr Lars Gramstad

Scientific Advice:

The applicant received Scientific Advice from the CPMP on 23 September 1999. The Scientific Advice pertained to part IV of the dossier.

Licensing status:

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 31 October 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 16 January 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 15 January 2001.
- During the meeting on February 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 27 February 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 16 May 2001.
- The summary report of the inspection carried out at the manufacturing site between 23-26 April 2001 of the Searle Barceloneta facility in Puerto Rico was issued on 21 June 2001.
- The Rapporteur and Co-Rapporteur circulated the Joint Assessment Report on the company's responses to the List of Questions to all CPMP members on 3 July 2001.
- During the CPMP meeting on 24-26 July 2001, the List of Outstanding Issues to be addressed in writing and during an Oral Explanation was discussed and agreed by the CPMP.
- The company submitted the responses to the List of Outstanding Issues on 19 September 2001.
- The Rapporteur and Co-Rapporteur circulated the Joint Assessment Report on the company's written responses to the List of Outstanding Issues to all CPMP members on 2 October 2001.
- During the CPMP meeting on 17 October 2001, outstanding issues were addressed by the applicant during a hearing before the CPMP.
- The company, Pharmacia Europe EEIG, provided on 14 November 2001, a letter of undertaking on the follow-up measures to be fulfilled as requested by the CPMP.
- During the meeting on 13-15 November 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 Dynastat on 15 November 2001.

- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 22 March 2002.