**BACKGROUND INFORMATION ON THE PROCEDURE**

## 1. Submission of the dossier

The company Takeda Europe R & D Centre Limited submitted on 30 March 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Glustin, through the centralised procedure. After agreement by the CPMP on 22 October 1998, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr. Mary Teeling Co-Rapporteur: Prof. Cristina Sampaio

**Licensing status:**

At the time of the application, a new drug application was filed in the following countries: Japan (25 December 1996) and USA (15 January 1999).

## 2. Steps taken for the assessment of the product

- The procedure started on 23 April 1999
- The Rapporteur's first assessment report was circulated to all CPMP Members on 18 June 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 20 June 1999
- During the meeting on 27-29 July 1999 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 28 July 1999
- The Applicant submitted the responses to the CPMP consolidated list of questions on 5 October 1999
- The summary report of the inspection carried out at the manufacturing site between 1-5 November 1999 of the Takeda Chemical Industries, Osaka, Japan, was issued on 21 November 1999
- Supplementary information was provided by the Applicant on 22 November 1999
- The Rapporteur and Co-Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP Members on 24 November 1999
- The list of outstanding issues to be addressed by the Applicant during an oral explanation was adopted by the CPMP on 16 December 1999 and revised on 15 January 2000
- Written explanations were provided by the Applicant on 14 January 2000
- During the CPMP meeting on 15 February 2000, outstanding issues were addressed by the Applicant during a oral explanation before the CPMP
- A list of outstanding issues to be addressed in writing and during an oral explanation by the Applicant was adopted by the CPMP on 16 March 2000
- Written explanations were provided by the Applicant on 9 May 2000
- The Rapporteur circulated a joint assessment report on the company's responses to the list of outstanding issues to all CPMP Members on 15 May 2000
- During the CPMP meeting on 23 May 2000, the outstanding issues were addressed by the Applicant during an oral explanation before the CPMP. The adoption of the Opinion was

postponed to June 2000 CPMP meeting in order to further revise the SPC and the post-marketing commitments

- Written explanations were provided by the Applicant on 12 June 2000
- The Rapporteur circulated a joint assessment report on outstanding CPMP issues to all CPMP Members on 19 June 2000
- During the meeting on 27-29 June 2000 the CPMP, in light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion by majority vote for granting a Marketing Authorisation to Glustin on 29 June 2000.