BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Ltd submitted on 28 April 2004 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Aclasta, through the centralised procedure. After agreement by the CHMP on 25 November 2003, 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 CHMP were:

Rapporteur:	Co-Rapporteur:
Dr Per Nilsson	Prof Magnus Johannsson

Scientific Advice:

The applicant received Scientific Advice from the CHMP on 16 November 2001, 27 January 2003 and 26 March 2004. The Scientific Advice pertained to clinical and non-clinical aspects 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 application was received by the EMEA on 28 April 2004.
- The procedure started on 17 May 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 23 July 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 22 July 2004.
- During the meeting on 13-16 September 2004, the CHMP 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 15 September 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 8 November 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 16 December 2004.
- The Rapporteurs’ Final Recommendation was circulated to the CHMP on 13 January 2005.
- During the meeting on 17-20 January 2005, the CHMP, 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 Aclasta on 20 January 2005. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 19 January 2005.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 15 April 2005.