BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Millennium Pharmaceuticals, Ltd submitted on 31 January 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Velcade, through the centralised procedure. After agreement by the CPMP on 21 January 2004, 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: Dr Markku Toivonen

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 24 February 2003.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 5 May 2003. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 28 April 2003.
- During the meeting on 24-26 June 2003, 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 June 2003.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 28 August 2003
- The GCP inspection relating to the clinical trial protocol M34100-025, requested by CPMP, was carried out at the following sites: Dr Ann Traynor, Northwestern University Medical School, Robert H. Lurie Cancer Center, 676 North St. Claire, Suite 850. Chicago, IL 60611, USA (inspected 8-12 Sep 2003) and Dr James Berenson, Cedars-Sinai Medical Center, Beverly Modular 1, 8700 Beverly Blvd., Los Angeles, CA 90048, USA, (inspected 15-19 Sep 2003). The final Integrated Inspection Report was issued on 12 November 2003.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 20 October 2003.
- During the CPMP meeting on 20 November 2003, the CPMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant.
- The applicant submitted the responses to the list of outstanding issues on 12 December 2003.
- During the meeting on 20-21 January 2004, 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 under exceptional circumstances to Velcade on 21 January 2004. The applicant provided the letter of undertaking on the specific obligations and follow-up measures to be fulfilled post-authorisation on 20 January 2004.