BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Novartis Europharm Limited submitted on 21 December 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Zometa, through the centralised procedure. After agreement by the CPMP on 24 June 1999, 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. Jens Ersbøll Co-Rapporteur: Prof. Silvio Garattini

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 21 January 2000.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 11 April 2000. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 31 March 2000.
- During the meeting on 23-25 May 2000 the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 26 May 2000.
- During the meeting on 23-25 May 2000 the CPMP decided to request an inspection of the manufacturing sites.
- The inspection was carried out between 8-11 August 2000 at the manufacturing sites of the finished product and the packaging site. The summary report of the inspection was issued on 12 September 2000.
- The company submitted the responses to the consolidated list of questions on 20 October 2000.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 24 November 2000.
- During the meeting on 12-14 December 2000 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 Zometa on 14 December 2000.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 March 2001.