

BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Baxter AG submitted on 20 September 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMA) for ADVATE, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr. M. Haase

Co-Rapporteur: Dr. F. Lekkerkerker

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 October 2002.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 23 December 2002. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 9 January 2003.
- During the meeting on 18-20 February 2003 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 20 February 2003.
- The company submitted the responses to the consolidated list of questions on 14 May 2003.
- The report of the testing of samples by the Paul Ehrlich Institut and the Rijksinstituut voor Volksgezondheid en Milieu (RIVM) was issued on 26 May 2003 and 13 May 2003.
- The Rapporteur circulated the response joint assessment report on the company's responses to the list of questions to all CPMP Members on 23 June 2003
- During the CPMP meeting on 22-24 July 2003, the CPMP agreed on the List of Outstanding Issues to be sent to the company.
- The company submitted the responses to the List of Outstanding Issues on 9 September 2003.
- During the meeting on 21-22 October 2003 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 ADVATE on 22 October 2003.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 2 March 2004.