

BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Serono Europe Limited submitted on 6 February 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMA) for Raptiva, 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 CHMP were:

Rapporteur: B. van Zwieten-Boot Co-Rapporteur: J. Ersbøll

Licensing status:

The product was not licensed in any country at the time of submission of the application. A new application was filed in the following countries: USA, where it has been subsequently authorised.

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 CHMP Members on 7 May 2003. The Co-Rapporteur's first assessment report was circulated to all CHMP Members on 12 May 2003.
- During the meeting on 24 – 26 June 2003 the CHMP 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 27 June 2003.
- The company submitted the responses to the consolidated list of questions on 16 December 2003.
- The Rapporteurs circulated the response assessment report on the company's responses to the list of questions to all CHMP Members on 2 February 2004.
- During the CHMP meeting on 24-26 February 2004, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CHMP members on 17 May 2004.
- During the CHMP meeting on 1-3 June 2004, outstanding issues were addressed by the applicant during an oral explanation before the CHMP. The CHMP subsequently adopted a list of remaining issues to be addressed in writing by the Applicant.
- The applicant submitted the written responses to the CHMP consolidated List of remaining issues on 7 June 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of remaining issues to all CHMP members on 15 June 2004.
- The applicant submitted the written responses to the CHMP consolidated List of outstanding issues on 16 April 2004.
- During the meeting on 22 – 23 June 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 Raptiva on 23 June 2004.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 September 2004.