BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Les Laboratoires SERVIER submitted on 16 April 2004 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Corlentor, through the centralised procedure. After agreement by the CHMP on January 21 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 CHMP were:

Rapporteur: Dr B. J. van Zwieten-Boot Co-Rapporteur: Dr. T. Kuitunen

Scientific Advice:

The applicant received Scientific Advice from the CHMP on 24 March 1999. The Scientific Advice pertained to 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 16 April 2004.
- The procedure started on 17 May 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 2 August 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 19 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 16 September 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 9 February 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 18 March 2005.
- During the CHMP meeting on 18 - 21 April 2005 the CHMP agreed on a list of outstanding issues to be addressed in an oral explanation and in writing by the applicant. The list of outstanding issues was sent to the applicant on 22 April 2005.
- The applicant submitted the written responses to the CHMP list of outstanding issues on 23 May 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the list of outstanding issues to all CHMP members on 9 June 2005.
- During the CHMP meeting on 20 - 23 June 2005, outstanding issues were addressed by the applicant during an oral explanation before the CHMP on 22 June 2005.
- The Rapporteurs circulated the Updated Joint Assessment Report to all CHMP members on 11 July 2005.
- During the meeting on 25 - 27 July 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 Corlentor. The applicant provided the letter of undertaking on the Follow-Up Measures to be fulfilled post-authorisation on 26 July 2005.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 25 October 2005.