BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Schering AG submitted on 2 June 2004 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Vasovist , through the centralised procedure. After agreement by the CHMP on 26 February 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 and the evaluation teams were:

Rapporteur: Dr Barbara van Zwieten-Boot Co-Rapporteur: Dr Ian Hudson

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

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 2 June 2004.
- The procedure started on 21 June 2004
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 7 September 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 6 September 2004.
- During the meeting on 19 October 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 19 October 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 22 April 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 26 May 2005.
- During the meeting on 23 June 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. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 20 June 2005.
- The CHMP opinion was forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 3 October 2005.