BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Schering AG submitted on 20 December 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) through the centralised procedure for Ventavis, which was designated as an orphan medicinal product EU/3/00/014 on 29 December 2000.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:
Rapporteur: Dr E. Abadie Co-Rapporteur: Prof S. Garattini

Orphan Drugs:

Iloprost was designated as an orphan medicinal product in the following indication: "Treatment of primary and of the following forms of secondary pulmonary hypertension: connective tissue disease pulmonary hypertension, drug-induced pulmonary hypertension, portopulmonary hypertension, pulmonary hypertension associated with congenital heart disease, chronic thromboembolic pulmonary hypertension."

Scientific Advice:

The applicant received Scientific Advice from the CPMP on 17 September 1998. The Scientific Advice pertained to part III and part IV 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 procedure started on 28 January 2002.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 15 April 2002. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 10 April 2002.
- During the meeting on 28 – 30 May 2002 the CPMP 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 30 May 2002.
- The company submitted the responses to the CPMP consolidated List of Questions on 12 November 2002.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 6 January 2003.
- During the CPMP meeting on 21 – 23 January 2003 the CPMP adopted a list of outstanding issues to be addressed by the applicant in writing and if necessary during an oral explanation. The list of outstanding issues was sent to the applicant on 24 January 2003.
- The applicant provided written information on these outstanding issues to all CPMP members on 27 February 2003.
- The Rapporteur/Co-Rapporteurs' joint review on the applicant's responses to the list of outstanding issues was circulated to all CPMP members on 11 March 2003.

- During the CPMP meeting on 18 – 19 March 2003 the CPMP adopted a list of outstanding issues to be addressed by the applicant in writing and during an oral explanation. The list of outstanding issues was sent to the applicant on 19 March 2003.
- The applicant provided written information on these outstanding issues to all CPMP members on 3 April 2003.
- The Rapporteur/Co-Rapporteurs' joint review on the responses to the list of outstanding issues was circulated to all CPMP members on 14 April 2003.
- During the CPMP meeting on 23 – 25 April 2003, outstanding issues were addressed by the applicant during a hearing before the CPMP on 24 April 2003.
- During the meeting on 20 – 22 May 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 under exceptional circumstances to Ventavis on 22 May 2003.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 16 September 2003.