BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Pfizer Limited submitted on 2 December 2004 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for REVATIO, which was designated as an orphan medicinal product EU/3/03/178 on 12 December 2003.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:
Rapporteur: Dr. Frits Lekkerkerker Co-Rapporteur: Prof. Fernando de Andres-Trelles

Orphan Drugs:

REVATIO was designated as an orphan medicinal product in the following condition: pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. The calculated prevalence of this condition was 1 per 10,000 EU population.

Pursuant to Article 8 of Regulation (EC) No. 141/2000 and Article 3 of Commission Regulation (EC) No 847/2000, the application contained a critical report addressing the possible similarity with authorised orphan medicinal products.

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 25 November 2004.
- The procedure started on 20 December 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 28 February 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 1 March 2005.
- The CHMP adopted a report on similarity of Revatio with Tracleer and Ventavis on 17 March 2005.
- During the meeting on 18 – 21 April 2005, 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 20 April 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 10 May 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 30 June 2005.
- Following receipt of applicant written clarifications on 14 July 2005, the Rapporteurs circulated an updated Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 22 July 2005.
- During the meeting on 25-28 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 under exceptional circumstances to Revatio on 27 July 2005. The applicant provided the letter of undertaking on the specific obligations and follow-up measures to be fulfilled post-authorisation on 27 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 28 October 2005.