BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Schering-Plough Europe submitted on 26 July 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Aerinaze, through the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 27 April 2006.
The legal basis for this application refers to:

A - Centralised / Article 10(b) / Fixed combination application.

The application submitted is a complete dossier composed of administrative information, complete quality data, non-clinical and clinical data based on applicants' own tests and studies and/or bibliographic literature substituting/supporting certain test(s) or study(ies)

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.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: Pieter Neels Co-Rapporteur: Heribert Pittner

2 Steps taken for the assessment of the product

- The application was received by the EMEA on 26 July 2006.
- The procedure started on 16 August 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 15 November 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 30 October 2006.
- During the meeting on 11-14 December 2006, 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 14 December 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 14 February 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 02 April 2007.
- The applicant submitted additional clarifications on 19 April 2007.
- The Rapporteurs circulated a revised Joint Assessment Report on 24 April 2007.
- During the CHMP meeting on 23-26 April 2007, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP list of outstanding issues on 2 May 2007
- The Rapporteurs circulated a Joint Assessment Report on the responses to the List of Outstanding issues on 15 May 2007.
- During the meeting on 21 -24 May 2007 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 Aerinaze on 24 May 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 22 May 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 30 July 2007.