BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Schering-Plough Europe submitted on 2 July 2004 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Noxafil, through the centralised procedure. After agreement by the CHMP on 20 March 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 Ian Hudson Co-Rapporteur: Dr Eric Abadie

Scientific Advice:

The applicant received Scientific Advice from the CHMP on 25 April 2001. The Scientific Advice pertained to clinical aspects of the dossier.

Licensing status:

A new application was filed in the following countries: USA.
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 July 2004.
- The procedure started on 19 July 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 1 October 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 5 October 2004.
- During the meeting on 15 – 18 November 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 18 November 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 15 March 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 28 April 2005.
- During the CHMP meeting on 23 – 26 May 2005, the CHMP agreed on a List of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant.
- The applicant submitted the responses to the CHMP List of outstanding issues on 15 June 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding Issues to all CHMP members on 5 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 Noxafil on 27 July 2005. 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.