BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Pierre Fabre Médicament submitted on 3 December 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Busilvex, through the centralised procedure. Busulfex was designated as an orphan medicinal product (EU/3/00/011) on 29 December 2000.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Gonzalo Calvo Rojas Co-Rapporteur: Rolf Bass

Licensing status:

Intravenous busulfan has been given a Marketing Authorisation in the USA (1999), in Canada (1999), in Israel (2000) and South Korea (2001).

2. Steps taken for the assessment of the product

- The procedure started on 26 March 2002
- The Rapporteur's first assessment report was circulated to all CPMP Members on 10 June 2002. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 5 June 2002
- During the meeting on 23 - 25 July 2002 the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 30 July 2002.
- The company submitted the responses to the consolidated list of questions on 23 January 2003.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 4 March 2003.
- During the meeting on 18 - 19 March 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 to Busilvex on 19 March 2003.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 9 July 2003.