BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Apotex Europe submitted on 6 February 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Exferrum, through the centralised procedure. During the procedure the name was first changed to Deferiprone Chiesi Farmaceutici and later to Ferriprox. After agreement by the CPMP on 19 November 1997, this medicinal product is referred to Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.

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

Rapporteur: E. Abadie Co-Rapporteur: J.F. Olalla Marañón

Licensing status:

The product was not licensed in any country inside or outside the EU at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 27 February 1998.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 13 May 1998.
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 26 May 1998.
- During the meeting on 23-24 June 1998 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 25 June 1998.
- The applicant submitted the responses to the consolidated list of questions on 9 October 1998.
- On 17 November 1998 the applicant withdrew the proposed tradename Exferrum and proposed the tradename Ferrex instead.
- The Rapporteur circulated the joint response assessment report on the applicant's responses to the list of questions to all CPMP Members on 23 November 1998.
- During the meeting on 15-17 December 1998 the CPMP agreed on a list of outstanding issues to be sent to the applicant. The final list of outstanding issues was sent to the applicant on 18 December 1998. In addition the CPMP rejected the proposed tradename Ferrex.
- The applicant submitted further responses to questions related to pre-clinical and clinical issues on 11 January 1999 and agreed to change the name of the product to Deferiprone Chiesi Farmaceutici.
- The Rapporteur circulated the response assessment report on the applicant's responses to the list of outstanding issues on 19 January 1999.
- During the CPMP meeting on 26-28 January 1999, outstanding issues were addressed by the applicant during an oral explanation before the CPMP.
- During the meeting on 26-28 January 1999 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 Deferiprone Chiesi Farmaceutici on 28 January 1999.
- On 24 March 1999 the applicant withdrew the proposed tradename Deferiprone Chiesi Farmaceutici and proposed the tradename Ferriprox instead.
- During the meeting on 22-24 April 1999 the CPMP accepted the tradename Ferriprox.

- On 30 April 1999 the CPMP was made aware of potentially new safety information on deferiprone, and in particular of the existence of a recent draft manuscript by Berdoukas et al, 1999, indicating that there could be a risk of having progression of hepatic fibrosis, even over a short period of time.
- This issue was discussed at the CPMP Meeting on 18-20 May 1999. On behalf of the CPMP, the CPMP Chairman sent a letter to the European Commission on 20 May 1999, informing the European Commision accordingly. The applicant was also requested to supplement the file with any additional information in his possession or to confirm that all currently available information relevant to this issue had been supplied during the evaluation process.
- The applicant sent two letters dated 26 May 1999 and 1 June 1999 to the CPMP regarding the issue of liver fibrosis.
- On 11 June 1999 the Rapporteur and Co-Rapporteur circulated reports on the information provided.
- In a letter dated 15 June, 1999, the Commission informed the EMEA that the decision making process had been suspended and requested the CPMP to clarify whether, in the light of the potentially new safety information, there were important new questions of a scientific or technical nature, which have not been addressed in the opinion of the Agency.
- The CPMP nominated relevant experts in the therapeutic area to participate in an ad-hoc expert group meeting, which was held on 21 June 1999. The expert group forwarded several recommendations to the CPMP.
- During the meeting on 22-23 June 1999 the CPMP accepted the recommendations of the ad-hoc expert group and, in the light of the overall data submitted and the scientific discussion within the Committee issued a revised positive Opinion for granting a Marketing Authorisation under exceptional circumstances to Ferriprox on 23 June 1999.
- The CPMP Opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 25 August 1999.