BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Helsinn-Birex Pharmaceuticals Ltd., submitted on 29 July 2003 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Aloxi, through the centralised procedure. After agreement by the CHMP on 23 January 2003, 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 and the evaluation teams were:

Rapporteur: Dr. Salmon Co-Rapporteur: Dr. Calvo Rojas

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 29 July 2003.
- The procedure started on 18 August 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 30 October 2003. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 29 October 2003.
- During the meeting on 17 December 2003, 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 17 December 2003.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 15 June 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 20 August 2004.
- During the CHMP meeting on 16 September 2004, 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 written responses to the CHMP List of Outstanding Issues on 15 October 2004 and asked for an oral explanation to address section 4.1 and 5.1 of the SPC.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Outstanding Issues to all CHMP members on 28 October 2004.
- During the CHMP meeting on 17 November 2004, outstanding issues on section 4.1 and 5.1 of the SPC were addressed by the applicant during an oral explanation.
- During the December 2004 meeting, 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 Aloxi on 15 December 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 14 December 2004.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 22 March 2005.