BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Janssen-Cilag International N.V. submitted on 12 July 2004 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for IONSYS, through the centralised procedure. After agreement by the CHMP on 13 October 2005, 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. Hudson Co-Rapporteur: Dr. Kuitunen

Scientific Advice:

The applicant received Scientific Advice from the CHMP on 26 February 1999. The Scientific Advice pertained to quality and clinical aspects of the dossier.

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 12 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 28 September 2004.
- During the meeting on 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 01 July 2005.
- The summary report of the inspection carried out at the manufacturing site Alza Corporation, Commercial Facility, Vacaville, CA, USA between 19 and 22 April 2005 was issued on 21 June 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 18 August 2005.
- During the CHMP meeting on 15 September 2005, 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 21 September 2005.
- The Rapporteurs circulated a Joint Assessment Report on the applicant’s responses to the List of outstanding issues to all CHMP members on 28 September 2005.
- The Rapporteurs circulated to all CHMP members a revised Joint Assessment Report on 10 October 2005.
- During the meeting on 13 October 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. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 12 October 2005.