BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Janssen-Cilag International NV submitted on 4 May 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Invega, through the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 14 December 2005.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application

The application submitted is a complete dossier:
composed of administrative information, complete quality data, non-clinical and clinical data based on applicants' own tests and studies and/or bibliographic literature substituting/supporting certain test(s) or study(ies).

Scientific Advice:
The applicant received Scientific Advice from the CHMP on 24 July 2003. The Scientific Advice pertained to quality, non-clinical and clinical aspects of the dossier.

Licensing status:
The product was not licensed in any country at the time of submission of the application.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:

Rapporteur: Tomas Salmonson Co-Rapporteur: Karl Broich

2 Steps taken for the assessment of the product

- The application was received by the EMEA on 4 May 2006.
- The procedure started on 24 May 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 8 August 2006 (Annex 4.1). The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 10 August 2006 (Annex 4.2).
- During the meeting from 18-21 September 2006, 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 21 September 2006 (Annex 4.3).
- The applicant submitted the responses to the CHMP consolidated List of Questions on 15 December 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 26 January 2007 (Annex 4.4).
- During the CHMP meeting from 19-22 February 2007, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant (Annex 4.5).
- The applicant submitted the responses to the CHMP list of outstanding issues on 27 March 2007.

- During the meeting from 23-26 April 2007, 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 Invega on 26 April 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 19 April 2007 (Annex 4.6).
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 25 June 2007.