1 BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Allergan Pharmaceuticals Ireland submitted on 26 April 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Ganfort, through the centralised procedure.

The legal basis for this application refers to:
Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application.

Scientific Advice:
The applicant did not seek scientific advice at the CHMP.

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 were:

Rapporteur Dr. S. Thirstrup Co-Rapporteur Dr. G. Calvo Rojas

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 26 April 2005.
- The procedure started on 18 May 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 27 July 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 04 August 2005.
- During the meeting on 12-15 September 2005, 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 16 September 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 16 December 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 24 January 2006.
- During the CHMP meeting on 20–23 February 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing and by the applicant.
- The applicant submitted written explanations to the CHMP consolidated List of Outstanding Issues on 1 March 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 08 March 2006.
- During the meeting on 20–23 March 2006, 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 Ganfort on 23 March 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 14 March 2006. The European Commission granted a marketing authorisation valid throughout the European Union for Ganfort on 19 May 2006.