BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Pharma Mar S.A. submitted on 27 July 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for Yondelis, which was designated as an orphan medicinal product EU/3/01/039 on 30 May 2001.Yondelis was designated as an orphan medicinal product in the following indication: treatment of soft tissue sarcoma. The calculated prevalence of this condition was 2 per 10,000 EU population.

The applicant applied for the following indication: treatment of patients with advanced soft tissue sarcoma after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents.

Protocol Assistance:
The applicant did not seek Protocol Assistance 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: **Jens Ersbøll** Co-Rapporteur: **Gonzalo Calvo Rojas**

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 27 July 2006.
- The procedure started on 16 August 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 31 October 2006.The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 30 October 2006.
- During the meeting on 11-14 December 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 14 December 2006.
- A clarification meeting with the Rapporteurs on the CHMP List of Questions was held on the 24 February 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 15 March 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 4 May 2007 and an updated Overview on 8 May 2007.
- During the CHMP meeting on 21-24 May 2007 the CHMP agreed on a list of outstanding issues to be addressed in writing and in an oral explanation by the applicant.
- The applicant submitted the responses to the CHMP consolidated list of outstanding issues on 13 June 2007.
- The Rapporteurs circulated an updated Joint Assessment Report on the applicant's responses to the list of outstanding issues to all CHMP members on 10 July 2007.
- During the meeting on 16-19 July 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 under exceptional circumstances to Yondelis on 19 July 2007. The applicant provided the letter of undertaking on the specific obligations and follow-up measures to be fulfilled post-authorisation on 19 July 2007.
- The CHMP adopted a report on similarity of Yondelis with Glivec and Sutent on 19 July 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 17 September 2007.