BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant TopoTarget A/S submitted on 27th July 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for Savene, which was designated as an orphan medicinal product EU/3/01/059 on 19 September 2001. Savene was designated as an orphan medicinal product in the following indication: Treatment of anthracycline extravasation. The estimated prevalence of this condition was approximately 0.03 in 10,000 persons in the Community, at the time the application for orphan designation was made.

The applicant applied for the following indication: "Treatment of anthracycline extravasation".

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 tests or studies.

Protocol Assistance

None.

Licensing status

The product was not licensed for treatment of anthracycline extravasation in any country at the time of submission of the application.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: Dr Eric Abadie Co-Rapporteur: Dr. Jens Ersbøll

2 Steps taken for the assessment of the product

- The application was received by the EMEA on 27 July 2005.
- The procedure started on 17 August 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 27 October 2005 (Annex 4.1). The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 1 November 2005.
- During the meeting on 14 December 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 15 December 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 17 February 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 24 March 2006.
- During the CHMP meeting on 27 April 2006, 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 2 May 2006.
- The Rapporteurs circulated the Final Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 19 May 2006
- During the meeting on 29 May-1 June 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 Savene on 1 June 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 23 May 2006.
- The European Commission granted a marketing authorisation valid throughout the European Union for Savene on 28 July 2006.