BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant m e d a c Gesellschaft für klinische Spezialpräparate mbH submitted on 4 May 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for Gliolan, which was designated as an orphan medicinal product EU/3/02/121 on 13 November 2002. Gliolan was designated as an orphan medicinal product in the following indication: Intra-operative photodynamic diagnosis of residual glioma. The calculated prevalence of this condition was 1 in 10,000 in EU population.

The applicant applied for the following indication visualisation of malignant tissue during surgery for malignant glioma.

Protocol Assistance:
The applicant received Protocol Assistance from the CHMP on 25 April 2003 and on 21 January 2005. The Protocol Assistance pertained to the clinical and quality aspects of the dossier respectively.

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: **Cristina Sampaio** Co-Rapporteur: **Michal Pirozynski**

1.2 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 22 August 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 15 August 2007.
- During the meeting on 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.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 22 December 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 23 February and an update on 28 February 2007.
- During the CHMP meeting on 19-22 March 2007 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 consolidated list of outstanding issues and in preparation for the SAG Oncology meeting on 20 April 2007.
- The Rapporteurs circulated the updated Joint Assessment Report on the applicant's responses to the CHMP on 4 May 2007.
- During a meeting of SAG Oncology on 11 May 2007, experts were convened to address questions raised by the CHMP.
- During the CHMP meeting on 21-24 May 2007 the CHMP agreed on a second list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP second consolidated list of outstanding issues on 6 June 2007.
- The Rapporteurs circulated a further updated Joint Assessment Report on the applicant's responses to the CHMP second list of outstanding issues on 13 June 2007.

- During the meeting on 18-21 June 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 Gliolan on 21 June 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 20 June 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 7 September 2007.