BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant AEA Technology QSA GmbH submitted on 28 April 2004 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Yttriga, through the centralised procedure. After agreement by the CHMP on 15 September 2005, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:
Rapporteur: Dr. Jens Ersboll Co-Rapporteur: Dr. Barbara van Zwieten-Boot

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.

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 28 April 2004.
- The procedure started on 19 July 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 17 October 2004 . The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 21 October 2004.
- During the meeting on 15-18 November 2004, 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 18 November 2004 .
- The applicant submitted the responses to the CHMP consolidated List of Questions on 13 April 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 23 May 2005.
- During the CHMP meeting on 23 June 2005, the CHMP agreed on a List of Outstanding Issues to be addressed in writing by the applicant.
- The applicant submitted their responses to the List of Outstanding Issues on 27 June 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Outstanding issues to all CHMP members on 26 August 2005.
- The Rapporteurs circulated a revised Joint Assessment Report on the applicant’s responses on 5 September 2005.
- During the meeting on 15 September 2005, 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 Yttriga on 15 September 2005. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 6 September 2005.