BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Wyeth Europa Ltd. submitted on 05 October 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for TORISEL, which was designated as an orphan medicinal product EU/3/03/365 on 06 April 2006. TORISEL was designated as an orphan medicinal product in the following indication: treatment of renal cell carcinoma. The calculated prevalence of this condition was 35 per 100,000 EU population, at the time of the designation.

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

The applicant applied for the following indication treatment of advanced renal cell carcinoma.

Information relating to Orphan Market Exclusivity

Similarity
Pursuant to Article 8 of Regulation (EC) No. 141/2000 and Article 3 of Commission Regulation (EC) No 847/2000, the application contained a critical report addressing the possible similarity with authorised orphan medicinal products.

Protocol Assistance
The applicant received Protocol Assistance from the CHMP on 16 September 2004. The Protocol Assistance pertained to quality and clinical aspects of the dossier.

Licensing status
TORISEL has been given a Marketing Authorisation in United States of America, for the treatment of advanced renal cell carcinoma on 30 May, 2007.

A new application was filed in the following countries: Canada, Switzerland, Australia, Japan, South Africa, Turkey, Taiwan, Mexico and Brazil.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:
Rapporteur: Harald Enzmann Co-Rapporteur: Barbara van Zwieten-Boot

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 05 October 2006.
- The procedure started on 25 October 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 16 January 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 19 January 2007.
- During the meeting on 20-22 February 2007, 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 23 February 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 11 May 2007.
- The summary report of the GCP inspection carried out at the following sites Professor Ingo Schmidt-Wolf (Bonn, Germany) on 05–08 February 2007, Professor Elżbieta Starosławska (Lublin, Poland) on 12-16 February 2007 and at sponsor site, Wyeth Research Division (Cambridge, MA, USA) on 13–16 March 2007 was issued on 25 May 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 26 June 2007.

- The CHMP adopted a report on similarity of TORISEL with Sutent and Nexavar on date 18 July 2007 (Appendix 1).
- During the CHMP meeting on 17-19 July 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 revised list of outstanding issues on 23 August 2007.
- During the meeting on 18-20 September 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 TORISEL on 20 September 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 19 September 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 19 November 2007.