1 BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Bayer HealthCare AG submitted on 7 September 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for Nexavar which was designated as an orphan medicinal product EU/3/04/207 on 29 July 2004. Nexavar was designated as an orphan medicinal product in the following indication: treatment of renal cell carcinoma. The calculated prevalence of this condition was approximately 3 per 10,000 EU population.

The applicant applied for the following indication: Nexavar is indicated for the treatment of patients with advanced renal cell carcinoma. The legal basis for this application refers to Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application, (i.e. complete dossier with administrative, quality, non-clinical and clinical data).

Scientific Advice

The applicant received Scientific Advice from the CHMP on 15 May 2003. The Scientific Advice pertained to clinical aspects of the dossier.

Licensing status:

A new application was filed in the following countries: USA

The Rapporteur and Co-Rapporteur appointed by the CHMP were:

Rapporteur: Tomas Salmonson Co-Rapporteur: Beatriz Silva Lima

CHMP Peer reviewers: Jens Ersbøll and Romaldas Maciulaitis

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 7 September 2005.
- The procedure started on 28 September 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 8 December 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 12 December 2005. During the meeting on 23-26 January 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 26 January 2006.
- The applicant submitted preliminary responses to the CHMP List of Questions in preparation of the SAG for Oncology on 13 February 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 20 February 2006.
- During a meeting of SAG Oncology on 9 March 2006 experts were convened to address questions raised by the CHMP. Answers and comments were given by the group on 22 March 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.
- The Rapporteurs circulated an updated Joint Assessment Report to all the CHMP members on 21 April 2006.
- During the meeting on 24-27 April 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 Nexavar on 27 April 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 25 April 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 19 July 2006.