BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Chiron Corporation Ltd. submitted on 1 December 2004 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for CUBICIN, through the centralised procedure. The eligibility to the centralised procedure by the CHMP was agreed upon on 16 September 2004.

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

Rapporteur: I. Hudson Co-Rapporteur: L. Mathiesen

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

Licensing status:

CUBICIN has been given a Marketing Authorisation in the USA on 12 September 2003 and in Israel on 13 July 2004.

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 1 December 2004.
- The procedure started on 20 December 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 25 February 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 1 March 2005.
- During the meeting on 18 – 21 April 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 21 April 2005.
- On 26 May 2005, a meeting was organised with the European Committee on Antimicrobial Susceptibility Testing (EUCAST) to discuss the breakpoints.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 8 July 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 12 August 2005.
- During the CHMP meeting on 12 – 15 September 2005, the CHMP agreed on a List of Outstanding Issues to be addressed in writing by the applicant.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of outstanding Issues to all CHMP members on 24 October 2005.
- During the meeting on 14 – 17 November 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 CUBICIN on 17 November 2005. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 16 November 2005.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 19 January 2006.