1. BACKGROUND INFORMATION ON THE PROCEDURE

1.1. Submission of the dossier

The applicant Neurim Pharmaceuticals EEC Ltd. submitted on 5 October 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Circadin, through the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 24 June 2005.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application

Scientific Advice:
The applicant received Scientific Advice from the CHMP on 25 July 2002. The Scientific Advice pertained to clinical aspects of the dossier.

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 and the evaluation teams were:
Rapporteur: Prof. C. Sampaio Co-Rapporteur: Dr. G. Aislaitner

1.2. Steps taken for the assessment of the product

- The application was received by the EMEA on 5 October 2005.
- The procedure started on 26 October 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 10 January 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 28 December 2005.
- During the meeting on 20-23 February 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 24 February 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 29 September 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 27 October 2006.
- During the CHMP meeting on 13-16 November 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing and 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 8 March 2007.
- During the CHMP meeting on 19-22 March 2007, outstanding issues were addressed by the applicant during an oral explanation before the CHMP.
- During the meeting on 23-26 April 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 Circadin on 26 April 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 25 April 2007.