1. BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Biocodex submitted on 25 April 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for Diacomit, which was designated as an orphan medicinal product EU/3/01/071 on 05 December 2001. Diacomit was designated as an orphan medicinal product in the following indication: Treatment of severe myoclonic epilepsy in infancy. The calculated prevalence of this condition was 0.4 per 10,000 EU population.

The applicant applied for the following indication: Severe Myoclonic epilepsy of infancy (Dravet's syndrome).

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

Protocol Assistance:

The applicant did not seek Protocol Assistance at the CHMP.

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

Rapporteur: Dr Ian. Hudson Co-Rapporteur: Prof Giuseppe Nisticò

Licensing status:

The product was not licensed in any country at the time of submission of the application.

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 25 April 2005.
- The procedure started on 18 May 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 28 July 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 28 July 2005.
- During the meeting on 12-15 September 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 15 September 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 21 April 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 02 June 2006.
- During the CHMP meeting on 26-28 June 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing and in an oral explanation by the applicant.
- During the CHMP meeting on 18-21 September 2006, outstanding issues were addressed by the applicant during an oral explanation before the CHMP.
- During the meeting on 16-18 October 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 conditional Marketing Authorisation to Diacomit on 18 October 2006. The applicant provided the letter of undertaking on the specific obligations and follow-up measures to be fulfilled post-authorisation on 17 October 2006.

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