COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Bio-Melatonine 3 mg film-coated tablets (melatonin)

NL/H/3579/001/DC

Date: 20 May 2019

This module reflects the scientific discussion for the non-approval of Bio-Melatonine 3 mg film-coated tablets. The procedure was finalised on 14 December 2016.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation for Bio-Melatonine 3 mg film-coated tablets from Pharma Nord ApS.

The indication applied for concerned the short-term treatment of jet-lag in adults.

The marketing authorisation was applied pursuant to Article 10(a) of Directive 2001/83/EC, a so called bibliographic application based on the well-established medicinal use of melatonin.

The concerned member state (CMS) involved in this procedure was Hungary.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to potential serious risk to public health as defined in the Guideline on the definition of a potential serious risk to public health in the context of Article 29(1) and (2) of Directive 2001/83/EC — March 2006 (2006/C 133/05).

Although efficacy has been demonstrated for the indication jet-lag and safety issues that were identified have been adequately addressed by SmPC warnings, it is considered that well-established use of the product has not fully been demonstrated. This was concluded for the reason that similarity between the product applied for and products mentioned in the literature was not completely shown. In addition, a major objection to the restricted part of the ASMF has not been solved.

Therefore, the Board concluded that the marketing authorisation for Bio-Melatonine 3 mg film-coated tablets cannot be granted. Agreement on this conclusion was reached with the CMS. The decentralised procedure was finalised with a negative outcome on 14 December 2016.