COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Amifampridine Inventia 10 mg tablets (amifampridine phosphate)

NL/H/5981/001/DC

Date: 5 June 2026

This module reflects the scientific discussion for the non-approval of Amifampridine Inventia 10 mg tablets. The procedure was finalised at 5 June 2025.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused a marketing authorisation for Amifampridine Inventia 10 mg tablets, from Inventia Healthcare B.V.

The indication applied for was the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.

The concerned member states (CMS) involved in this procedure were France and Germany.

The marketing authorisation was applied for pursuant to Article 10(1) of Directive 2001/83/EC.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to major objections (MO's) qualifying as 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):

Quality

No shelf life or storage condition can be assigned to the proposed drug product. The proposed shelf life of 18 months and proposed storage condition 'Store below 25°C' are not acceptable, as compliance with the dissolution limit Q=85% in 15 minutes has not been demonstrated during the stability studies for one of the three validation batches. Compliance at previous timepoints has not been demonstrated to propose a shorter shelf life. Hence, no shelf life or storage condition can be granted.

To clarify the major objection, a break-out session (BOS) was offered to the applicant at day 180. However, the break-out session on 19 May 2025 and the submitted data did not solve the MO.

The Board followed the advice of the assessors.

Therefore, the Board concluded that the marketing authorisation for Amifampridine Inventia 10 mg tablets cannot be granted. Agreement on this conclusion was reached with the concerned member states. The decentralised procedure was finalised with a negative outcome on 5 June 2025.