Medicines Evaluation Board

Public Assessment Report
Scientific discussion

Tolvaptan Glenmark 7.5 mg, 15 mg and 30 mg tablets
(tolvaptan)

NL/H/5848/001-003/DC

Date: 19 June 2026

This module reflects the scientific discussion for the non-approval of Tolvaptan Glenmark 7.5 mg, 15 mg and 30 mg tablets. The procedure was finalised on 31 October 2024.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused a marketing authorisation for Tolvaptan Glenmark 7.5 mg, 15 mg and 30 mg tablets, from Glenmark Arzneimittel GmbH.

The indications applied for included:
Tolvaptan Glenmark is indicated in adults for the treatment of hyponatremia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

This application has been assessed with The Netherlands as Reference Member State (RMS) and Germany, Italy, Norway, Spain and Sweden as concerned Member States (CMS).

The marketing authorisation was applied pursuant to Article 10(1) of Directive 2001/83/EC, which concerns a generic application.

The application was discussed in the Board meeting of 24 October 2024 (nr. 1064). A breakout session (BOS) was offered but declined by the applicant.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to a major objection 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), which was not considered resolved:

Clinical aspects
The proposed product and the reference product are considered products with specific formulation characteristics aimed at increasing bioavailability of the active substance tolvaptan. According to the EMA Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/ Corr ** of 2010) and the draft EMA product-specific Bioequivalence Guidance for tolvaptan, for this preparation, both a BE study under fasted and fed conditions should be provided. Reason for this requirement is that in such cases the food effect may critically depend on the manufacturing process and cannot a priori assumed to be comparable with that of other products. Data provided by the applicant indicate that the 30 mg tablet is not bioequivalent under fed conditions. Therefore, the provided information is considered insufficient to support registration.

Based on the submitted data for the current application, it is considered that bioequivalence is not established. The benefit/risk of the product is considered negative.

Therefore, the Board concluded that the marketing authorisation for Tolvaptan Glenmark 7.5 mg, 15 mg and 30 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 31 October 2024.