COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Glycopyrronium bromide AllGen 1 mg/5 ml oral solution (glycopyrronium bromide)

NL/H/5955/001/DC

Date: 11 November 2025

This module reflects the scientific discussion for the non-approval of Glycopyrronium bromide 1 mg/5 ml oral solution. The procedure was finalised at 21 January 2025.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused a marketing authorisation for Glycopyrronium bromide 1 mg/5 ml oral solution, from All-Gen Pharmaceuticals & Generics B.V.

The indication applied for included:
Symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged three years and older with chronic neurological disorders.

The concerned member states (CMS) involved in this procedure were Germany, Ireland and Italy.

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

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to major objections 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):

Non-Clinical
The grounds for refusal are:

- The genotoxic potential of glycopyrronium bromide has not been sufficiently addressed.
- The reproductive and developmental toxicity of glycopyrronium bromide have not been sufficiently addressed.

To clarify the remaining major objections (MOs) at day 180, a break-out session (BOS) was held. In this meeting, it was stressed that the provided data should meet the requirements for a well-established use application as laid down in Annex I of Directive 2001/83/EC and the Notice to Applicants (Volume 2A Procedures for marketing authorisation Chapter 1 Marketing Authorisation, July 2019). The BOS and the data submitted by the MAH did not resolve the remaining non-clinical MOs.

Therefore, the Board concluded that the marketing authorisation for Glycopyrronium bromide 1 mg/5 ml oral solution cannot be granted. Agreement on this conclusion was reached with the concerned member states. The decentralised procedure was finalised with a negative outcome on 21 January 2025.