COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Rosuvastatine/Ezetimibe STADA 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg and 40 mg/10 mg film-coated tablets (rosuvastatin calcium/ezetimibe)

NL/H/5124/001-004/DC

Date: 24 June 2025

This module reflects the scientific discussion for the non-approval of Rosuvastatine/Ezetimibe STADA 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg and 40 mg/10 mg film-coated tablets. The procedure was finalised on 24 August 2022.

I. INTRODUCTION

The Medicines Evaluation Board has refused a marketing authorisation for Rosuvastatine/Ezetimibe STADA 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg and 40 mg/10 mg film-coated tablets, from Stada Arzneimittel AG.

The indications applied for included:

- Primary Hypercholesterolaemia: indicated as adjunct to diet for treatment of primary hypercholesterolemia as substitution therapy in adult patients adequately controlled with the individual substances given concurrently at the same dose level as in the fixed dose combination, but as separate products.
- Prevention of Cardiovascular Events: indicated to reduce the risk of cardiovascular events as substitution therapy in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), in adults who are adequately controlled with the individual substances given concurrently at the same dose level as in the fixed combination medicinal product, but as separate products.

The concerned member states (CMS) involved in this procedure were:

<u>Rosuvastatine/Ezetimibe 5 mg/10 mg</u>
Belgium, Denmark, Finland, Iceland, Italy, Luxembourg and Sweden.

<u>Rosuvastatine/Ezetimibe 10 mg/10 mg and 20 mg/10 mg</u>
Belgium, Czechia, Denmark, Finland, Iceland, Italy, Luxembourg, Portugal, Spain and Sweden.

<u>Rosuvastatine/Ezetimibe 40 mg/10 mg</u>
Belgium, Czechia, Denmark, Finland, Iceland, Italy, Luxembourg and Sweden.

The marketing authorisation was applied for pursuant to Article 10b, fixed dose combination (FDC) of Directive 2001/83/EC. Fixed dose combinations (pursuant to article 10b of Directive 2001/83/EC) contain active substances from medicinal products already authorised in the EEA individually, but not yet authorised in combination for therapeutic purposes. In these kind of applications, pre-clinical and clinical data relating to the combination are provided and it is not necessary to provide pre-clinical and clinical data relating to each individual active substance.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The dossier submitted by the MAH for this application has been assessed, the submitted data regarding the quality, safety and efficacy of Rosuvastatin Ezetimibe STADA is considered acceptable. The data provide sufficient information for a positive benefit risk for a substitution indication. However, a marketing authorisation could not be granted due to the reasons described below.

By separate decisions of 4 September 2019, 10 October 2019, 22 October 2019, 24 October 2019 and 11 November 2019 (primary decisions), the MEB granted marketing authorisations for a combination medicine combining the active substances of ezetimibe and atorvastatin. In the Netherlands, pursuant to Article 7:1 of the General Administrative Law Act, an interested party can object to a decision of an administrative authority. Based on this, an interested party has presented an objection to the Medicines Evaluation Board (MEB) against the multiple granting of a marketing authorisation based on a 10b legal basis for the same fixed dose combination (ezetimibe and atorvastatin combined in a single medicinal product). The MEB declared this objection unfounded and the interested party appealed against this decision. The appeal was then heard by the District Court Noord-Holland (Haarlem, the Netherlands). The MEB submitted a statement of defence and the interested party submitted an explanation of the appeal. Based on this information, the District Court declared the appeal of the interested party well-founded. Consequently, the MEB applied this ruling analogously to the current application for Rosuvastatin Ezetimibe STADA.

The MEB finalised the procedure for Rosuvastatin/Ezetimibe STADA with the following conclusion:

Based on a recent decision by the court in Haarlem (the Netherlands), the RMS cannot grant marketing authorisations for Rosuvastatin Ezetimibe STADA following the current application based on Article 10b of Directive 2001/83/EC (NL/H/5124/001-004/DC). The combination of the active substances rosuvastatin and ezetimibe, combined in a single medicinal product based on article 10b, has already been granted a marketing authorisation in the Netherlands to another company, therewith excluding any new applications based on article 10b for the same combination of drug substances. The current marketing authorisation application is therefore considered non-approvable in the RMS (NL).

The Board concluded that the marketing authorisation for Rosuvastatine/Ezetimibe STADA 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg and 40 mg/10 mg film-coated tablets cannot be granted. The RMS (NL) has communicated this conclusion to the CMDh, the Concerned Member States and to the applicant. The decentralised procedure was finalised with a negative outcome on 24 August 2022.