Medicines Evaluation Board

Public Assessment Report

Scientific discussion

Dexamface 5 mg, tablets (dexamphetamine sulphate)

NL/H/5396/001/DC

Date: 15 June 2026

This module reflects the scientific discussion for the non-approval of Dexamface 5 mg, tablets. The procedure was finalised on 18 August 2022.

1 Introduction

Based on the review of the quality, safety and efficacy data, the Member States have refused a marketing authorisation for Dexamface 5 mg, tablets from ACE Pharmaceuticals B.V.

The indication applied for was:
for attention-deficit/hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years when response to previous methylphenidate treatment is considered clinically inadequate. A comprehensive treatment program typically includes psychological, educational and social measures.

Diagnosis should be made according to DSM-5 criteria or the guidelines in ICD-10 and should be based on a comprehensive evaluation of the patient.

Dexamfetamine is not indicated in all children with ADHD and the decision to use dexamfetamine must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the child's age and potential for abuse, misuse or diversion. Treatment should be under the supervision of a specialist in childhood and/or adolescent behavioural disorders.

The marketing authorisation was applied pursuant to Article 10a of Directive 2001/83/EC, which concerns a well-established use application.

The concerned member state involved in this procedure was Germany.

The application was discussed in the Board meeting of 28 Juli 2022 (nr. 1008). A breakout session (BOS) was held in August 2022.

2 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).

According to article 10a of Directive 2001/83/EC, the applicant had to make plausible that the compositions and release characteristics of the products used in the literature studies (supporting the clinical and non-clinical information) are comparable to those of the proposed product (in other words: that the literature results could be transferred to the newly proposed product).

A major objection (MO) for approval was raised, as appropriate bridging (direct bridging) was not established between the new product and the products described in the used literature. Instead, 'indirect bridging' was used via a product that was

described in too little detail (non-pivotal) in the literature. For this, the MAH submitted dissolution data comparing Dexamface 5 mg with an in-house manufactured capsule-product that approximates the products reported in the used literature. Additionally, the MAH provided argumentation for this approach, justifying why any small differences would not be relevant.

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

Therefore, the Board concluded that the marketing authorisation for Dexamface 5 mg, tablets cannot be granted. Agreement on this conclusion was reached with the concerned member state. The decentralised procedure was finalised with a negative outcome on 18 August 2022.