COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Tadalafil ELC 2.5 mg, film-coated tablets

(tadalafil)

NL/H/4387/001/DC

Date: 26 August 2019

This module reflects the scientific discussion for the non-approval of Tadalafil ELC 2.5 mg, film-coated tablets. The procedure was finalised at 7 May 2019.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation Tadalafil ELC 2.5 mg, film-coated tablets, from ELC GROUP s.r.o.

The indication applied for concerns the treatment of erectile dysfunction in adult males.

The marketing authorisation was applied pursuant to Article 10(1) of Directive 2001/83/EC, claiming essential similarity with the innovator product Cialis 2.5 mg, film-coated tablets which has been registered in the EEA through centralised procedure (EMEA/H/C/000436) by Eli Lilly Nederland B.V. since 12 November 2002.

The concerned member state in this procedure was Spain.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to 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

The biowaiver of strength for the 2.5 mg strength cannot be accepted. A major objection has been raised based on the first set of dissolution data which did not show similarity of the 2.5 mg tablets versus the 20 mg biobatch. The additional comparison of the combined dissolution data from 3 sets of 8 x 2.5 mg tablets with the 20 mg biobatch at pH 1.2 by f2-calculation does not support the biowaiver of strength either and the provided justification does not justify the observed differences.

Therefore, the Board concluded that the marketing authorisation for Tadalafil ELC 2.5 mg, film-coated 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 7 May 2019.