CBG MEB

Public Assessment Report

Scientific discussion

Elores 1.5 g/vial, powder for solution for injection or infusion

(ceftriaxon sodium/sulbactam sodium)

NL/H/2981/001/DC

Date: 10 March 2017

This module reflects the scientific discussion for the non-approval of Elores 1.5 g/vial, powder for solution for injection or infusion. The procedure was finalised on 10 May 2016.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation for Elores 1.5 g/vial, powder for solution for injection or infusion from Venus Pharma GmbH.

The indication applied for concerns Urinary Tract Infections (complicated and uncomplicated).

The marketing authorisation was applied for pursuant to Article 10b of Directive 2001/83/EC, a fixed combination of ceftriaxone (third generation cephalosporin) and sulbactam (beta-lactamase inhibitor). This concerns essentially a new product containing two known actives not previously available for co-administration.

The Concerned Member States involved in the procedure were Belgium, Estonia, Hungary, Latvia, Lithuania, Luxembourg, Malta, Romania, Slovakia and Slovenia.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorization could not be granted due to major objections qualifying as potential serious risks 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).

In the fixed dose combination Elores the addition of sulbactam is thought to extend the spectrum of activity of ceftriaxone against almost all common extended spectrum beta-lactamases (ESBLs) and metallo-beta-lactamases (MBLs), thereby limiting the need to use carbepenems.

The applicant submitted a single trial to support the efficacy and safety of this fixed dose combination and to demonstrate the adequacy of the proposed dose in the claimed indications. Several inconsistencies in the submitted study shed doubt on the GCP compliance of this study. Moreover, methodological limitations make that the study is insufficiently robust to support the claims.

The application was discussed in the meetings of the Medicines Evaluation Board of the Reference Member State on 2 July 2015, 4 February 2016 and 7 April 2016. It was concluded that there is currently insufficient ground to base a benefit-risk assessment upon. Adequacy of the proposed dose regimen should be demonstrated in a well designed and properly conducted confirmative randomised controlled comparative trial. The trial should comply with existing guidelines and provide essential information on the safety and efficacy of Elores. Robust evidence of the added benefit of sulbactam to ceftriaxone in the claimed indications needs to be provided. The Board concluded that the marketing authorisation for this medicinal product cannot be granted. Agreement on this conclusion was reached with the Concerned Member States. The decentralised procedure was finalised with a negative outcome on 10 May 2016.