Public Assessment Report

Scientific discussion

Piperacillin/Tazobactam Bradex 4 g/0.5 g, powder for solution for infusion

(piperacillin/tazobactam)

NL/H/3874/001/DC

Date: 13 November 2018

This module reflects the scientific discussion for the non-approval of Piperacillin/Tazobactam Bradex 4 g/0/5 mg, powder for solution for infusion. The procedure was finalised at 29 March 2018.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation for Piperacillin/Tazobactom Bradex 4 mg/0.5 mg, powder for solution for infusion from Bradex S.A., Pharmaceutical Products.

The indications applied for concern treatment of the following infections in adults and children over two years of age:

Adults and adolescents:
- Severe pneumonia including hospital-acquired and ventilator-associated pneumonia
- Complicated urinary tract infections (including pyelonephritis)
- Complicated intra-abdominal infections
- Complicated skin and soft tissue infections (including diabetic foot infections)

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Piperacillin/Tazobactam Bradex may be used in the management of neutropenic patients with fever suspected to be due to a bacterial infection.

Children 2 to 12 years of age:
- Complicated intra-abdominal infections

Piperacillin/Tazobactam Bradex may be used in the management of neutropenic children with fever suspected to be due to a bacterial infection.

The marketing authorisation was applied pursuant to Article 10(1) of Directive 2001/83/EC.

The Concerned Member States involved in the procedure were Belgium, France, Hungary and Luxembourg.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted due to a major objection 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).

The manufacturing process of the drug product has been adequately validated according to relevant European guidelines on six full scaled batches of the intermediate product and three full scaled batches of the final product. However, an inadequate batch formula for the intermediate product was applied, which has been revised during the procedure. Batch data and process validation justifying the use of the revised batch formula, which no longer includes the use of overages, are not available. It has not been demonstrated that the revised batch

formula yields a finished product with a consistent and acceptable quality. The application is therefore not approvable. The decentralised procedure was finalised with a negative outcome on 29 March 2018