CBG MEB

Public Assessment Report

Scientific discussion

Methylprednisolon Eurogenerics 32 mg tablets

(methylprednisolone)

NL/H/3387/003/DC

Date: 18 July 2016

This module reflects the scientific discussion for the non-approval of Methylprednisolon Eurogenerics 32 mg tablets. The procedure was finalised on 24 February 2016.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation for Methylprednisolon Eurogenerics 32 mg tablets, from Eurogenerics N.V.

Methylprednisolone is a corticosteroid which is used to treat a wide range of conditions.

The marketing authorisation was applied for pursuant to Article 10(1) of Directive 2001/83/EC, a generic application with reference to the innovator product Medrol 32 mg tablets.

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

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorization 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 aspects

A difference in dissolution profile between two batches at pH 4.5 was observed and raised concerns about batch-to-batch consistency. In response, the applicant tightened the hardness specification. However, this was not confirmed through submission of comparative dissolution profiles of three production scale batches. The applicant was not able to provide the required dissolution data before the end of the decentralised procedure. A commitment to provide the data post-approval, but prior to marketing of the drug product was not accepted.

The application was discussed in the meeting of the Medicines Evaluation Board of the RMS on 17 February 2016. It was concluded that the root cause of the inconsistent dissolution profiles had not been fully identified. In addition, there is no supporting evidence to confirm that the proposed corrective action resolves the inconsistent dissolution profiles. It is thus not ascertained that the quality of the product is consistently controlled. The Board concluded that the marketing authorisation for Methylprednisolon Eurogenerics 32 mg tablets cannot be granted. Agreement on this conclusion was reached with the Concerned Member States. The decentralised procedure was finalised with a negative outcome on 24 February 2016.