CBG MEB

Public Assessment Report

Scientific discussion

Clopidogrel/Acetylsalicylzuur Apotex 75 mg/75 mg and 75 mg/100 mg, film-coated tablets

(clopidogrel/acetylsalicylic acid)

NL/H/3860/001-002/DC

Date: 13 March 2018

This module reflects the scientific discussion for the non-approval of Clopidogrel/Acetylsalicylzuur Apotex 75 mg/75 and 75 mg/100 mg, film-coated tablets. The procedure was finalised at 30 November 2017.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused granting a marketing authorisation for Clopidogrel/Acetylsalicylzuur Apotex 75 mg/75 mg and 75 mg/100 mg, film-coated tablets, from Apotex Europe BV.

The indication applied for concerns*:* the prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid. The product is a fixed-dose combination medicinal product for continuation of therapy in:

- Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction) including patients undergoing a stent placement following percutaneous coronary intervention.
- ST segment elevation acute myocardial infarction in medically treated patients eligible for thrombolytic therapy

The marketing authorisation was applied pursuant to Article 10(a) of Directive 2001/83/EC, a so called bibliographic application based on the well-established medicinal use of the fixed-dose combination of clopidogrel and acetylsalicylic acid.

The concerned member states in this procedure were Belgium, Luxembourg and only for the 75 mg/100 mg strength Poland.

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

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

Pharmacokinetics

Bridging to literature data is insufficiently supported. Comparable bioavailability to the products mentioned in literature cannot be concluded due to the observed 63% difference in acetylsalicylic acid C_{max} in the bioequivalence study. The MAH was not able to explain this difference using literature data.

Therefore, the Board concluded that the marketing authorisation for Clopidogrel/Acetylsalicylzuur Apotex 75 mg/75 mg and 75 mg/100 mg, film-coated 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 30 November 2017.