IPAR

IRISH MEDICINES BOARD

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Co-Amoxiclav 500mg/100mg Powder for Solution for Infusion & Injection
Co-Amoxiclav 1000mg/200mg Powder for Solution for Injection and Infusion

AMOXICILLIN SODIUM
POTASSIUM CLAVULANATE

PA 1457/001/001-002

The Public Assessment Report reflects the scientific conclusion reached by the Irish Medicines Board (IMB) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the IMB for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the IMB leading to the approval of the medicinal product for marketing in Ireland.

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the IMB has granted a marketing authorisation for Co-Amoxiclav 500 mg/100 mg Powder for Solution for Injection and Infusion and Co-Amoxiclav 1000 mg/200 mg Powder for Solution for Injection and Infusion, from Fannin Ltd.

This application for a marketing authorisation was submitted in accordance with Article 10(1) of Directive 2001/83/EC and is referred to as a 'generic' application. Co−Amoxiclav 500 mg/100 mg Powder for Solution for Injection and Infusion and Co−Amoxiclav 1000 mg/200 mg Powder for Solution for Injection and Infusion have the same qualitative and quantitative composition in terms of the active substance, and the same pharmaceutical form, as Augmentin Intravenous 500 mg/100 mg Powder for Solution for Injection or Infusion and Augmentin Intravenous 1000 mg/200 mg Powder for Solution for Injection or Infusion.

The Summary of Product Characteristics for (SPC) for this medicinal product is available on the IMB's website at www.imb.ie

Name of the product	Co-Amoxiclav 500 mg/100 mg Powder for Solution for Injection and Infusion and Co-Amoxiclav 1000 mg/200 mg Powder for Solution for Injection and Infusion
Name(s) of the active substance(s) (INN)	Amoxicillin Sodium Potassium Clavulanate
Pharmacotherapeutic classification (ATC code)	J01CR
Pharmaceutical form and strength(s)	500 mg/100 mg ; 1000 mg/200 mg
Marketing Authorisation Number(s) in Ireland (PA)	PA 1457/1/1 and PA 1457/1/2
Marketing Authorisation Holder	Fannin Ltd

II QUALITY ASPECTS

II.1. Introduction

This application is for Co-Amoxiclav 500 mg/100 mg Powder for Solution for Injection and Infusion and Co-Amoxiclav 1000 mg/200 mg Powder for Solution for Injection and Infusion.

II.2 Drug substance

The active substances are amoxicillin sodium and potassium clavulanate, established active substances described in the European Pharmacopoeia, and are manufactured in accordance with the principles of Good Manufacturing Practice (GMP)

The active substance specifications are considered adequate to control the quality and meet current pharmacopoeial requirements. Batch analytical data demonstrating compliance with these specifications have been provided.

II.3 Medicinal product

P.1 Composition

Active substance	
Amoxicillin	500 mg/1000 mg as amoxicillin sodium
Clavulanic acid	100 mg/200 mg as potassium clavulanate

Brief description of the dosage form:

Powder for solution for injection and infusion. White to almost white crystalline powder.

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of good manufacturing practice (GMP) at suitably qualified manufacturing sites.

The manufacturing process has been validated according to relevant ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients)

Not applicable

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for powder for injection and infusion and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data for a number of batches from the proposed production site have been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 Packaging material

The product is presented as a vial.
Evidence has been provided that the glass complies with Ph. Eur.

P.7 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines demonstrating the stability of the product for 3 years when stored below 25 ºC.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Co-Amoxiclav 500 mg/100 mg Powder for Solution for Injection and Infusion and Co-Amoxiclav 1000 mg/200 mg Powder for Solution for Injection and Infusion.

III NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is a generic formulation of Augmentin on the European market. No new pre-clinical data have been submitted. As such, no pre-clinical assessment has been made on the application. This is acceptable for this type of application.

IV CLINICAL ASPECTS

IV.1 Introduction

Co-Amoxiclav is a well known active substance with established efficacy and tolerability.

The content of the SmPC approved during the national procedure is in accordance with that accepted for the reference product Augmentin marketed by the marketing authorisation holder (MAH), GlaxoSmthKline (Ireland Ltd).

For this generic application for Co-Amoxiclav injection and infusion, the applicant has submitted no bioequivalence studies and in accordance with relevant bioequivalence guidelines, such studies are not required.

The SmPC is based on the SmPC agreed for Augmentin following a recent Article 30 Referral.

IV.2 Pharmacokinetics

No studies were submitted. The applicant performed a review of pharmacokinetics of Co-Amoxiclav.

IV.3 Pharmacodynamics

No studies were submitted.

IV.4 Clinical Efficacy

No studies were submitted. The applicant performed a review of efficacy of licensed indications.

IV.5 Clinical Safety

No studies were submitted. The applicant performed a review of safety of licensed indications.

IV.6 Discussion on the clinical aspects

This is a generic application in which the applicant documents the similarity of their product to the reference product and is not required to repeat other clinical studies.
The license is based on that of the reference product.

V OVERALL CONCLUSIONS

Benefit/Risk Assessment and Recommendation

Co-Amoxiclav 500 mg/100 mg and 1000 mg/200 mg Powder for Solution for Infusion and Injection are generics of Augmentin. Augmentin is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

The MAH has provided written confirmation that systems and services are in place to ensure compliance with their pharmacovigilance obligations.

The IMB, on the basis of the data submitted considered that Co-Amoxiclav has a satisfactory risk/benefit profile and therefore granted a marketing authorisation.