Public Assessment Report

Scientific discussion

Fluoxetine Amdipharm 10 mg, 20 mg, 30 mg and 40 mg, hard capsules

(fluoxetine hydrochloride)

NL/H/3535/001-004/DC

Date: 10 April 2018

This module reflects the scientific discussion for the approval of Fluoxetine 60 mg hard capsules. The procedure was finalised on 28 November 2016.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have refused a marketing authorisation for Fluoxetine Amdipharm 10 mg, 20 mg, 30 mg and 40 mg, hard capsules, from Amdipharm Limited.

The indications applied for concerns:
Adults:

- Major depressive episodes
- Obsessive-compulsive disorder
- Bulimia nervosa: Fluoxetine is indicated as a complement of psychotherapy for the reduction of binge-eating and purging activity

Children and adolescents aged 8 years and above

- Moderate to severe major depressive episode, if depression is unresponsive to psychological therapy after 4-6 sessions. Antidepressant medication should be offered to a child or young person with moderate to severe depression only in combination with a concurrent psychological therapy.

The marketing authorisation was applied for pursuant to Article 10(1) (the 20 mg strength) and Article 10(3) (the 10 mg, 30 mg and 40 mg strengths) of Directive 2001/83/EC. Article 10(3) is a hybrid application, as the 10 mg, 30 mg and 40 mg strengths of the product are cross-referred to the 20 mg strength of the reference product Prozac 20 mg hard capsules which has been registered in the United Kingdom by Eli Lilly since 25 November 1988.

The concerned member state involved in this procedure were Belgium, France, Luxembourg and the United Kingdom

II. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisation could not be granted as after examination of the provided data, it has been found that submission bioequivalence studies results could not be waived to the 10 mg, 20 mg, 30 mg and 40 mg strengths'.

Quality aspects
Similarity of the profiles of the 10 mg, 20 mg and 40 mg strength versus the 60 mg biobatch was not shown at pH 6.8. For these strengths, the similarity in dissolution compared with the 60 mg strength was not demonstrated in the subsequent rounds, as the additional data provided were not of sufficient quality.
The biowaiver for the 30 mg strength is not considered acceptable taking into account the dissolution results at pH 6.8 of the 10/20/40 mg strengths. Since the 10, 20, 30 and 40 mg are dose proportional, and the criteria for a biowaiver for the 10, 20 and 40 mg are not met, a biowaiver for the 30 mg strength is also not considered justified.

Therefore, the Board concluded that the marketing authorisation for Fluoxetine 10 mg, 20 mg, 30 mg and 40 mg hard capsules from Amdipharm Limited cannot be granted. Agreement on this conclusion was reached with the concerned member state. The decentralised procedure was finalised with a negative outcome on 28 November 2016.