NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Regulatory Directive on the Registration of Cyproheptadine (2mg, 4mg) and Cyproheptadine in Combination with Multivitamin Formulations

1.0. Purpose:

This Regulatory Directive aims to control the registration of Cyproheptadine (2mg, 4mg) and Cyproheptadine in combination with Multivitamin formulation especially in Pediatrics due to the risks associated with product safety.

Cyproheptadine is an antihistamine which is used to alleviate symptoms associated with allergic reactions, such as itching and hives. It has an appetite-stimulating side-effect. Combining Cyproheptadine with a multivitamin in one formulation may be convenient for individuals with both prescription for specific health reasons. However, the appetite stimulating side-effects of this formulation has been widely abused resulting in overdose with exaggerated side-effects and risk of kidney toxicity.

2.0. Scope:

This Regulatory Directive applies to locally manufactured formulations of Cyproheptadine (2mg, 4mg) and Cyproheptadine in combination with multivitamin in which New, Renewal & Variation applications are processed.

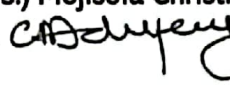
3.0. Directive Details:

Cyproheptadine (2mg, 4mg) and Cyproheptadine in combination with multivitamin in formulations will only be registered by the Agency under the following conditions:

- Cyproheptadine 4mg formulation will be classified as POM only.
- Multivitamin can only be formulated in combination with Cyproheptadine 2mg. The product will be classified as a POM

This directive is imperative because of the risk of kidney toxicity due to abuse of the appetite stimulating side-effect of Cyproheptadine in combination with Multivitamin formulations.

While Cyproheptadine is commonly used for its off-label indication of appetite stimulation and addition of multivitamin or an amino acid may add to the benefits derived from such use, there are no sufficient data on the safety of such combination especially in children.

Approved By:
Director-General (NAFDAC)
Prof. (Mrs.) Mojisola Christianah Adeyeye
Signature:  **Date:** 1/7/2024

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RD: Regulatory Directive
XX: First two letters of the first two words of the document title