DOCUMENT TITLE: REGULATORY DIRECTIVE ON DISCONTINUED REGISTRATION OF KETOCONAZOLE TABLET		
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NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Regulatory Directive on Discontinued Registration of Ketoconazole Tablet

1.0. Purpose:

This regulatory directive stipulates the discontinued registration of Ketoconazole tablets due to the risks associated with product safety.

The use of Ketoconazole tablets has the risk of causing hepatotoxicity. Ketoconazole may cause liver damage, sometimes serious enough to require liver transplantation or cause death. In view of its risk factors, patients placed on ketoconazole tablets are advised to undertake a liver function test after two (2) weeks of use, a requirement that is not feasible in our clime hence the need to discontinue its registration.

2.0. Scope:

This Regulatory Directive applies to locally manufactured and imported Ketoconazole tablets.

3.0. Directive Details:

NAFDAC no longer accepts New, Renewal and Variations applications for locally-manufactured and imported Ketoconazole tablets.

Approved By:

Director-General (NAFDAC)

Prof. (Mrs.) Mojisola Christianah Adeyeye

Signature: **Date:** 1/7/2024

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