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

Regulatory Directive on Discontinued Registration of Halofantrine formulations

1.0. Purpose:

This Regulatory Directive stipulates the discontinued registration and use of Halofantrine formulations in the treatment of Malaria.

Halofantrine is an antimalarial drug which belongs to the phenanthrene class of compounds that includes quinine and lumefantrine. The compound was registered by the Agency for the treatment of malaria. However, the use of single compound formulation for the treatment of malaria is discouraged by the World Health Organization.

2.0. Scope:

This Regulatory Directive applies to locally manufactured and imported Halofantrine formulations (all strengths and dosage forms).

3.0. Directive Details:

NAFDAC no longer accepts New, Renewal And Variations applications for locally manufactured and imported Halofantrine formulations (all strengths and dosage forms).

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 of the first two words of the document title