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

Regulatory Directive on Discontinued Registration of Chloroquine Injection

1.0. Purpose:

This Regulatory Directive aims to Clarify the registration status of Chloroquine Injection.

Chloroquine is a member of an important series of chemically related antimalarial agents, the quinoline derivatives. Chloroquine is administered orally as chloroquine phosphate. It can also be given by intramuscular injection as chloroquine hydrochloride. Chloroquine is not effective against all strains of malaria, or against malaria in areas where the infection has been resistant. It is generally not used for Plasmodium falciparum as there is widespread resistance to it. Plasmodium falciparum accounts for more than 96% of malaria cases in Nigeria. Although chloroquine was primarily used for the treatment of malaria in Nigeria, it is also used for the treatment of hepatic amoebiasis, lupus erythematosus and rheumatoid arthritis.

Since the product has proved to be in-effective for treatment of the major cause of malaria in Nigeria, the Agency has deemed it fit to discontinue its registration and use for that indication.

2.0. Scope:

This Regulatory Directive applies to locally manufactured and imported Chloroquine Injection with the discontinued indication for use.

3.0. Directive Details:

NAFDAC no longer accepts applications for locally manufactured and imported Chloroquine Injection with the discontinued indication for use.

The Agency will however continue to register locally manufactured and imported chloroquine injections with approved indication being only for the treatment of hepatic amoebiasis, lupus erythematosus and rheumatoid arthritis.

The discontinuation is imperative because of persistent use in the country for the treatment of malaria despite chloroquine not being effective in the treatment of the major cause of Malaria (P. falciparum). It is important to note that Chloroquine is not part of the National Standard Treatment Guidelines for malaria.

Approved By:

Director-General (NAFDAC)

Prof. (Mrs.) Mojisola Christianah Adeyeye

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

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