DOCUMENT TITLE: REGULATORY DIRECTIVE ON REGISTRATION OF DICLOFENAC SODIUM 50MG, PARACETAMOL 325MG, CHLORZOXAZONE 250MG FIXED DOSE COMBINATION		
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NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Regulatory Directive on the discontinued Registration of Diclofenac Sodium 50mg, Paracetamol 325mg, Chlorzoxazone 250mg Fixed Dose Ccombination

1.0. Purpose:

This regulatory directive stipulates the discontinued registration of Fixed Dose Ccombination (FDC) of Diclofenac Sodium 50mg, Paracetamol 325mg & Chlorzoxazone 250mg due to the risks associated with product safety.

Diclofenac is a Non-Steroidal Anti-inflammatory Drug (NSAID), Paracetamol is an analgesic with antipyretic properties while Chlorzoxazone is a muscle relaxant. The therapeutic justification for this FDC has not been established leading to a ban of this FDC in India. Iirrational therapy leads to Adverse Drug Reactions (ADR) and eexcessive use of paracetamol leads to Hepatotoxicity.

2.0. Scope:

This Regulatory Directive applies to locally manufactured and imported Fixed Dose Combination of Diclofenac Sodium 50mg, Paracetamol 325mg & Chlorzoxazone 250mg.

3.0. Directive Details:

NAFDAC no longer accepts New, Renewal and Variations applications for locally manufactured and imported Diclofenac Sodium 50mg, Paracetamol 325mg & Chlorzoxazone 250mg FDC.

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.