DOCUMENT TITLE: REGULATORY DIRECTIVE ON THE DISCOUNTINUED REGISTRATION OF ACECLOFENAC SODIUM 100MG, PARACETAMOL 500MG, CHLORZOXAZONE 250MG FIXED DOSE CCOMBINATION		
DOC. REF. NO.:	EFFECTIVE DATE:	REVIEW DUE DATE:
NAFDAC-RDAP-023-00	01-07-2024	30-06-2029

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

Regulatory Directive on the discontinued Registration of Aceclofenac Sodium 100mg, Paracetamol 500mg, Chlorzoxazone 250mg Fixed Dose Combination.

1.0. Purpose:

This Regulatory Directive stipulates the discontinued registration of Fixed Dose Combinations (FDC) of Aceclofenac Sodium 100mg, Paracetamol 500mg & Chlorzoxazone 250mg due to the risks associated with product safety.

Aceclofenac is a Non-Steroidal Anti-inflammatory Drug (NSAID); Paracetamol is an analgesic with antipyretic properties while Chlorzoxazone is a muscle relaxant with mechanism of action at the Central Nervous System. The therapeutic justification for this FDC has not been established leading to a ban of this FDC in India. Irrational therapy leads to Adverse Drug Reactions (ADR) and excessive use of paracetamol leads to Hepatotoxicity.

2.0. Scope:

This Regulatory Directive applies to locally manufactured and imported Fixed Dose Combination of Aceclofenac Sodium 100mg, Paracetamol 500mg and Chlorzoxazone 250mg.

3.0. Directive Details:

NAFDAC no longer accepts New, Renewal and Variations applications for locally manufactured and imported Aceclofenac Sodium 100mg, Paracetamol 500mg and Chlorzoxazone 250mg FDC.

Approved By:

Director-General (NAFDAC)

Prof. (Mrs.) Mojisola Christianah Adeyeye

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

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