

DOCUMENT TITLE: REGULATORY DIRECTIVE ON REGISTRATION OF DICLOFENAC SODIUM 50MG, PARACETAMOL 325MG, CHLORZOXAZONE 250MG FIXED DOSE COMBINATION		
DOC. REF. NO.:	EFFECTIVE DATE:	REVIEW DUE DATE:
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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 Combination**

**1.0. Purpose:**

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

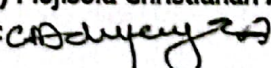
Diclofenac is a Non-Steroidal Anti-inflammatory Drug (NSAID), Paracetamol is an analgesic with antipyretic properties while Chlorzoxazone is a muscle relaxant. The therapeutic justification for this FDC has not been established leading to a ban of this FDC in India. Irrational therapy leads to Adverse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