DOCUMENT TITLE: REGULATORY DIRECTIVE ON DISCONTINUED REGISTRATION OF DICLOFENAC POTASSIUM 100MG TABLETS		
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NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Regulatory Directive on Discontinued Registration of Diclofenac Potassium 100mg formulations

1.0. Purpose:

This Regulatory Directive aims to discontinue the registration of Diclofenac Potassium 100mg formulation due to the potential risks associated with product safety.

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) used to treat mild to moderate pain, or signs and symptoms of osteoarthritis or rheumatoid arthritis. Diclofenac is available in two (2) different salt forms; Diclofenac Sodium & Diclofenac Potassium. The potassium salt has faster rate of absorption and onset of action, it should therefore not be given at a high dose of 100mg to avoid excessive high plasma concentrations that can result in hyperkalemia.

Further, the innovator of Diclofenac has only registered 50mg of Diclofenac Potassium. Generic manufacturers should not be able to register higher doses of Diclofenac Potassium 100mg formulation.

2.0. Scope:

This Regulatory Directive applies to locally manufactured and imported Diclofenac Potassium 100mg formulations.

3.0. Directive Details:

NAFDAC no longer accepts New, Renewal And Variation applications of the locally manufactured and imported Diclofenac Potassium 100mg formulations. The discontinuation is imperative because Potassium salt has an immediate/quick release pharmacodynamic properties hence it should only be given at a lower strength (50mg) to avoid hyperkalemia which results in muscle weakness and serious heart problems.

Approved By:

Director-General (NAFDAC)

Prof. (Mrs.) Mojisola Christianah Adeyeye

Signature: [signature] **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