MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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When replying please quote our ref No:

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16th April, 2020

To:

All Marketing Authorization Holders (MAHs)

Through'

The Local Technical Representatives (LTRs)

RE: REVOCATION OF MARKETING AUTHORIZATION FOR BULK-PACKED MEDICINES

TAKE NOTICE that from the date of this circular, the Pharmacy and Poisons Board ("the Board") shall not permit manufacture, importation, sale and distribution of medicines packaged in bulk pack sizes.

The Board shall only permit the manufacture, importation, sale and distribution of **unit-of-use packaged** medicines.

For the avoidance of doubt;

"*Bulk packaging*" contains one type of medicine per package intended for multiple single doses. These includes product packaged in a container closure system that is not given whole to the patient i.e. where re-packing is needed;

"*unit-of-use package*" means medicine that contains a quantity designed and intended to be dispensed directly to a patient or patients for a specific use without modification except for the addition of a prescription label by a dispensing pharmacist. Examples of such packages are blister packs, compliance packs, course-of-therapy packs and vials containing a 30-day supply or a quantity of medication appropriate for specific disease state among others;

Therefore,

1. With effect from 31st December 2020, marketing authorization of bulk-packed medicines shall stand revoked. Any retention of such products for 2021 shall not be valid;

2. Any bulk-packed batches of products currently in stock or in circulation shall be allowed to be consumed to expiry, to ensure uninterrupted access;

3. To ensure compliance, manufacturing authorization of local manufacturers for the year 2021 shall exclude any bulk packaging of Finished Pharmaceutical Products (FPPs).

In this regard, affected MAHs are required to make appropriate variation and/or notification of the marketing authorization status of affected products in Kenya.

Failure to comply with this circular shall lead to appropriate regulatory action including recall of any affected product batches.

Dr. F. M. Siyoi
CHIEF EXECUTIVE OFFICER

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Copy to: **Director General,**
Ministry of Health

Chief Executive Officer,
Kenya Medical Supplies Authority

Chief Executive Officer,
Mission for Essential Drugs and Supplies

Chief Executive Officer,
Medical Superintendent of all Hospitals (Private/Public)