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REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINE ON

IMPORTATION OF UNREGISTERED MEDICINAL SUBSTANCES

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Abbreviations and acronyms

PPB	Pharmacy and Poisons Board
CAP 244	Chapter 244 pharmacy and poison's Act

Glossary of terms

The definitions provided below apply to the words and phrases used in this guideline. The following definitions are provided to facilitate interpretation of the guideline.

Medicinal Substance

Medicinal substance as defined in CAP 244 means any medicine, product, article, or substance, which is claimed to be useful for any of the following purposes:

(a) Treating, preventing or alleviating disease or symptoms of disease;

(b) Diagnosing disease or ascertaining the existence, degree or extent of a physiological condition; or

(c) Preventing or interfering with the normal operation of a physiological function whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of the function in human beings or animals;

Unregistered medicinal substance

These are Pharmaceutical products that do not have a marketing authorization

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1. INTRODUCTION

1.1 Background

The amount of medicinal substance imported into Kenya for personal-use is normally small, both in size and value. This occurs especially when a patient seeks medical treatments not available in Kenya. It is thus the responsibility of the Pharmacy and Poisons Board to protect the public from fraudulent or otherwise illegal medical treatments in foreign and domestic businesses. It is noted that some countries do not regulate or restrict the exportation of health products and as such people who order from these businesses may not be afforded the protection they deserve from those entities.

The main situations when unregistered medicinal substances maybe imported into Kenya include (list not exhaustive):

- Patients or relatives mailing medicinal substances to Kenya in response to a prescription-like order to allow continuation of a therapy initiated abroad.

- Patients or relatives who carry medicinal substances in their personal baggage in response to a prescription-like order to allow continuation of a therapy initiated abroad.

- With increasing international travel and world trade, people may purchase medicinal substances abroad for personal use or on behalf of the individual requiring the medication that may not be registered in Kenya.

In certain situations, a healthcare practitioner may prescribe to a patient medicinal substance that may not be registered in Kenya after attending an international continuous professional education.

2.0 Legal Mandate.

The Board is mandated in law under CAP 244 of the Pharmacy and Poisons Act to control the importation and exportation of health products and technologies. This is outlined in section 3B subsection 2 (b) of the functions of the Board.

The Act further provides formulation of rules and regulations pertaining to importation and exportation under section 44 subsection 1 (ff).

The rules give provision for importation of part 1 poison, restriction on the importation or manufacture of specified drugs, exportation of drugs and poisons and exemptions.

3.0 Scope

To provide guidance for the importation of unregistered medicinal substance for personal-use regulated by the Pharmacy and Poisons Board.

4.0 Importation of unregistered medicinal substance

Pharmacy and Poisons Board has enforcement regulations on health products that are personally carried, shipped by a person, non-commercial representative of a consignee from foreign medical facility where a person has undergone treatment abroad. PPB shall undertake due diligence before allowing entry of such shipments. This may include examining the background of the shipment, risk-assessment, and purpose of the medicinal substance before making final determination.

PPB will allow importation of an unregistered medicinal substance in

Kenya in the following situations:

- Importation of medicinal substances carried through as personal baggage in response to a prescription order to allow continuation of a therapy initiated abroad.

- Importation of medicinal substances mailed in response to a prescription order to allow continuation of a therapy initiated abroad.

- Requests by expatriate(s) temporarily residing in Kenya whose medication may not be sourced locally.

- Prescription order from a registered healthcare practitioner or duly registered Pharmacy/Hospital/Clinic on patient name basis.

5.0 Personal Baggage with unregistered medicinal substances

Upon examination by a custom's officer and discovery that medicinal substances are in the personal baggage, the PPB officers at the responsible port of entry shall be notified by the customs official(s) for inspection and verification.

Inspection and verification shall entail determination of the purpose of the medications, quantities, expiry date and relevant supporting documents such as prescription from a duly registered doctor or letter of duty of care by a medical doctor.

Ordinarily, a 3-month supply shall be allowed for medicines for personal use.

Where in his/her assessment the PPB inspector determines that, based

on the quantities presently available, an import permit is required, the same shall be communicated to the passenger and the consignment shall hence with be detained at the designated place in the baggage hall.

The next steps shall entail application of the right type of permit and provision of the appropriate supporting documents as out-lined in the import and export guideline (Reference No. CEO/EIU/GUD/001).

Where in his/her assessment determines that violations to CAP 244 have been committed, a regulatory action shall be initiated such as seizure of the medicinal substances, destruction and disposal of the medicinal substance at the owner(s) cost or prosecution.

6.0 Mail shipments with unregistered medicinal substance

PPB has responsibility to monitor all mail importations. It is expected that an officer from mail services (including couriers services) will examine a parcel and will set it aside if it appears to contain a medicinal substance that is regulated by PPB or appears to represent a health fraud or unknown risk to health. PPB personnel shall audit those parcels set aside in accordance with the prescribed requirements below.

7.0 Conditions for importation of unregistered medicinal substance.

1. Medicinal substance should be used for personal treatment or treatment of an immediate family member. The recipient should not resupply (resell or give) the medicinal substance to any other patient.

2. Prescription order for a medicinal substance from a registered healthcare practitioner or duly registered Pharmacy/Hospital/Clinic on named patient basis. The recipient health facility should not resupply (resell or give) the medicinal substance to any other patient.

3. All imports of an unregistered medicinal substance must obtain an import permit on a consignment basis. Each import permit is specific to a single medicinal substance or treatment as indicated in the prescription.

4. Maximum allowable quantity of an unregistered medicinal substance to be imported at one time should be not more than ninety (90) day supply based on the directions for use at the maximum dose

recommended by the manufacturer. In case more than 3-month supply is required at the one time, a duly registered Kenyan healthcare practitioner should support in writing such an application of the permit.

5. Medicinal substances should be kept in their original retail packaging or Hospital/Pharmacy dispensed packaging with the labels intact that clearly indicate the name and content of the medicinal substance.

6. Medicinal substances should be supplied in packaging written in English or Swahili language, including the package inserts and product labels.

7. Medicinal substances containing ingredients that are controlled like narcotic, psychotropic substances, anabolic/androgenic steroids or precursors chemicals, importation require other the relevant permits as required under the laws in the country of origin and Kenya.

8. Records must be maintained for all unregistered medicinal substances imported, which must be made readily available for inspection to the Pharmacy and Poisons Board.

8.0 Documentation Requirements

(a) A formal request for importation addressed to the Registrar, PPB with a clear justification as to why such a medicinal substance **cannot be sourced locally.**

(b) Relevant **commercial invoice or bill** of purchase of medicinal substance from the exporting country.

(c) Copy of Prescription or Hospital/Clinic Purchase Order having the healthcare practitioner's details on a named patient basis.

(d) Any other document determined appropriate as per the import and export guideline (Reference No: CEO/EIU/GUD/001).

9.0 Process Steps

(a) Declaration to PPB at port of entry of a medicinal substance in mail, personal baggage or from named patients in a registered health facility.

(b) PPB personnel to scrutinize and verify whether the accompanied documentation fulfils the prescribed requirements above.

(c) Where a permit is determined appropriate, the application procedure shall follow as out-lined in the import/export guideline of the Board.

REVISION HISTORY

Revision No:	Date	Author(s)	Section(s) revised	Description of change	Approvals
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References

(1) US FDA Regulatory Procedures Manual - April 2013, Chapter 9, Import Operations and Actions;

(2) SADC guidelines on import and export procedures for pharmaceutical health products, June 2006;

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(4) Guidelines for Importation and Export of Pharmaceuticals, National Drug Authority, Uganda;

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(6) Health Products under the Food and Drugs Act and its Regulations, Health Canada;

(7) UK MHRA: The supply of unlicensed medicinal health products ("specials");

(8) Guidelines to apply for approval to import an unregistered medicinal product, Health Sciences Authority, Singapore;

(9) Marketing Authorization of Pharmaceutical Products with special reference to Multisource (Generic) products: WHO/DMP/RGS/98.5;