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REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

DRAFT REQUIREMENTS FOR IMPORTATION OF UNREGISTERED MEDICINAL SUBSTANCES FOR PERSONAL USE IN KENYA

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Acknowledgements

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Preface

Pharmacy and Poisons Board has recognized that some conditions cannot be treated locally. Thus some patients may seek medical treatment not available in Kenya. It is however the responsibility of the Pharmacy and Poisons Board to protect the public from fraudulent or otherwise illegal medical treatments in foreign and domestic businesses. In general, the Pharmacy and Poisons Board discourages the use of unregistered medicinal substance in Kenya because such treatments may be promoted to individuals who believe that treatments available abroad will be effective in the treatment of serious conditions like cancer etc. Because some countries do not regulate or restrict the exportation of health products, people who order from these businesses may not be afforded the protection of either foreign or Kenyan laws

Legal framework

The Pharmacy and Poisons Board is empowered by section 44(1) of the Pharmacy and Poisons Act, Chapter 244 Laws of Kenya to regulate medicinal substances imported into Kenya.

Abbreviations

PPB: Pharmacy and Poisons Board
CAP 244: Chapter 244 Laws of Kenya

Definitions:

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;

Scope

To provide guidance for the importation of unregistered medicinal substance for personal-use regulated by the Pharmacy and Poisons Board. Medicinal substances imported for commercial or promotional use are not subject to these requirements.

Introduction

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. In general, the Pharmacy and Poisons Board discourages the use of unregistered medicinal substance in Kenya because such treatments may be promoted to individuals who believe that treatments available abroad will be effective in the treatment of serious conditions like cancer etc. Because some countries do not regulate or restrict the exportation of health products, people who order from these businesses may not be afforded the protection of either foreign or Kenyan laws.
The main situations when unregistered medicinal substances maybe imported in 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.

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, or shipped from foreign medical facility where a person has undergone treatment abroad. PPB uses discretion to allow entry of such shipments. It is important to note that this **should not be interpreted** as an approval to bring in unregistered medicinal substances. The discretion used by PPB personnel involves examining the background of the shipment, risk, and purpose of the medicinal substance before making a final decision.

PPB will only allow importation of an unregistered medicinal substance in Kenya in the following situations (list not exhaustive):

- Patients who seek medical treatments not available in Kenya.
- 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.
- Prescription order from a registered healthcare practitioner or duly registered Pharmacy/Hospital/Clinic on patient name basis.

Personal Baggage with Unregistered Medicinal Substance

There will be no examination of personal baggage by PPB at the port of entry. The examination of personal baggage is the responsibility of Customs and Immigration Officials. It is expected that a Customs and Immigration Official will notify PPB officers at the port of entry when they detect a shipment of a medicinal substance regulated by PPB or appears to represent a health fraud or an unknown risk to health. When such items in personal baggage are brought to PPB's attention, PPB personnel at point of entry will use discretion, on a case-by-case basis, in accordance with the prescribed requirements below.

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.

Conditions for importation of unregistered medicinal substance

- Medicinal substance should not be ordered over the Internet, including dietary supplements and herbal preparations.
- 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.
- 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.
- 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.
- Maximum allowable quantity of a unregistered medicinal substance to be imported at one time should be not more ninety (90) day supply based on the directions for use at the maximum dose recommended by the

manufacturer. In case more than ninety (90) day supply is required at the one time, a duly registered Kenyan healthcare Practitioner should support in writing such an application of the permit.

- 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.
- Medicinal substances should be supplied in packaging written in English or Swahili language, including the package inserts and product labels. For a first-time importation, these packaging documents should be submitted to the Directorate of Product Evaluation and Registration for review and approval.
- 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.
- The validity of the permit shall be three (3) months from the date of issuance.
- Records must be maintained for all unregistered medicinal substances imported, which must be made readily available for inspection by the Pharmacy and Poisons Board.

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) For each to be imported medicinal substance, state the following;

• Name and full address of the Patient, Company or Health Facility. • Country of origin. • Mode of shipment (sea, air, road) • Destination port of entry • Expected date of arrival • Quantity of each medicinal substance (see conditions above for maximum allowable quantity). • Unit and total value for each product being imported. • Trade or proprietary name of the medicinal substance.	• International Non Proprietary name of the Active Ingredient in the medicinal substance. In case a medicinal substance contains more than one active ingredient, the name of each ingredient should be stated. • Strength of the Active Ingredient if applicable. In case a medicinal substance contains more than one active ingredient, the strength of each ingredient should be stated. • Indication of the medicinal substance • Batch number of the medicinal substance. • Manufacturing and expiring date if applicable. • Storage conditions of the product.

(d) Copy of Prescription or Hospital/Clinic Purchase Order having the healthcare practitioners details on a named patient basis.

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 fulfills the prescribed requirements above. PPB personnel will use discretion, on a case-by-case basis, in accordance with the conditions provided above, in deciding whether to release the baggage, request for a sample, quarantine the medicinal substance, or take other appropriate action necessary.
(c) Target processing timeline to regulatory decision excluding stop-clock is Five (5) working days from the date of notification to Pharmacy and Poisons Board. The stop-clock stops when PPB requests for clarification or additional information with regard to the application.
(d) Medicinal substances that not meeting the above criteria will be rejected with the reason(s) for rejection being stated clearly.

References/Bibliography

(1) US FDA Regulatory Procedures Manual - April 2013, Chapter 9, Import Operations and Actions
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(4) Guidelines for Importation and Export of Pharmaceuticals, National Drug Authority, Uganda
(5) Guidance Document on the Import Requirements for
(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

Authors / contributors

- Selected Pharmacy and Poisons Board personnel
- Selected Members from stakeholders

Revision History

Revision No:	Date	Author	Section(s) revised	Description of change	Approvals
0	10 Sep, 2015	Anthony Toroitich	Draft Guideline For Importation Of Unregistered Medicinal Substances In Kenya	-	Draft
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