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REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

DRAFT GUIDELINE FOR IMPORTATION OF ORPHAN MEDICINAL SUBSTANCES IN KENYA

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This guideline represents the current thinking of the Pharmacy and Poisons Board on the application of import procedures for orphan medicinal substance as identified by the current laws and regulations. It is intended only to provide guidance and does not create of confer any rights for or any private persons and does not operate to bind Pharmacy and Poisons Board or the public.

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Preface

Rare diseases affect a few numbers of patients in the population. Patients suffering from rare diseases deserve access to the same quality of medicinal products as other patients. Pharmacy and Poisons Board has recognized that some conditions are so rare that it would not be financially worthwhile for pharmaceutical industry to invest in marketing the medicinal substance that treat these conditions. It is thus important to develop a guideline for importation of orphan medicines. The main objective of this guideline is to provide importers and exporters of medicinal substance with the necessary information to enable them comply with the law and regulations governing importation orphan medicinal substances into Kenya.

Legal framework

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. Pharmacy and Poisons Board had the responsibility for determining whether or not an orphan medicinal substance offered for importation is in compliance with or in violation of the Pharmacy and Poisons Act.

Abbreviations

PPB: Pharmacy and Poisons Board
CAP 244: Chapter 244 Laws of Kenya
API: Active Pharmaceutical Ingredient
GMP: Good Manufacturing Practices

Definitions

For the purpose of this guidance document the following acronyms and definitions are used:

Active Pharmaceutical Ingredient (API): Any substance or mixture of substances that is intended for use in the manufacture of a medicinal substance and that, when used in the production of a medicinal substance, becomes an active ingredient of the product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure and the function of the body.

Dosage Form: The final physical pharmaceutical form of the medicinal substance, which may be used by the consumer without requiring any further manufacturing.

Exportation: means the act of sending out or causing any goods to be taken out of a Kenyan International Territorial borders.

Good Manufacturing Practices (GMP): In this document refers to the Harmonized Technical Guidelines of GMP in the East African Community, and the interpretive guidelines on the subject published by Pharmacy and Poisons Board.

Importation: means the act of bringing or causing any goods to be brought into Kenyan International Territorial borders.

Manufacturer: A company that carries out operations such as production, packaging, repackaging, labeling and re-labeling of medicinal substances.

Medicinal substance: Under the *Pharmacy and Poisons Act CAP 244* this means any medicine, product, article, or substance, which is claimed to be useful for any of the following purposes:

(a) Diagnosing disease or ascertaining the existence, degree or extent of a physiological condition; or
(b) 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;
(c) Treating, preventing or alleviating disease or symptoms of disease;

Orphan medicine is a medicinal substance that is intended to treat, prevent or diagnose a rare disease. It is thus non-commercially viable product that cannot be supplied for treatment, prevention or diagnosing another disease or condition. For the purpose of this guideline, a medicinal substance is considered an orphan medicine if the product to which the disease is indicated for affects less than 50,000 Kenyans.

Rare disease is a life threatening, seriously debilitating, or serious and chronic condition that affects a relatively small number of patients.

Scope

To provide guidance for the importation of orphan medicinal substances regulated by the Pharmacy and Poisons Board. Unregistered Medicinal substances and parallel imported medicinal substances are not subject to these guidelines.

Introduction

Public health concerns require that patients suffering from rare diseases in the population gain access to the same quality, safety and efficacy of medicinal products as other patients. Pharmacy and Poisons Board has recognized that some conditions are so rare that it would not be financially worthwhile for pharmaceutical industry to invest in marketing the medicinal substance. The main objective of this guideline is to provide importers and exporters of medicinal substance with the necessary information to enable them comply with the law and regulations governing importation orphan medicinal substances into Kenya.
Pharmacy and Poisons Board may permit any person or company to import an orphan medicinal substance if it will be used by a medical practitioner who has prescribed the medicine for the treatment of a patient under his/her care.

Importation of Orphan Medicinal Substance

Most orphan medicinal substances used in the treatment of rare diseases have no marketing authorization in Kenya because pharmaceutical industry do not have financially motivation to invest in marketing such medicinal substance.

Conditions for importation of an Orphan medicinal substance

- Medicinal Substance should not hold any marketing authorization in Kenya.
- A competent medicine regulatory authority should approve medicinal Substance for use as an orphan medicinal substance either from the country of origin or from any other country where the orphan medicinal substance had been used.
- Medicinal Substance in the Pharmacy and Poisons Board, Directorate of Product Evaluation and Registration list of Orphan Medicinal Substances.
- Medicinal substances must meet all applicable requirements of the Pharmacy and Poisons Board and its Regulations, including, but not limited to
    - Labeling requirements,
    - Wholesale Dealers Licence, or authorization to conduct a clinical trail; and
    - GMP requirements.
- 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.
- Medicinal substance must be submitted at least fifteen (15) working days before the expected date of arrival of the consignment to avoid incurring demurrage charges caused by delays in processing import permits.

- The validity of the permit shall be twelve (12) months from the date of issuance.
- Medicinal Substances must be imported through the authorized gazetted Ports of Entry and Exit. The Kenya Gazette Notice No. 8370, Legal Notice No. 69 of 2010 lists the following Ports of Entry and Exit: Jomo Kenyatta International Airport (JKIA), Inland container Depot (ICD), Embakasi, Inland container Depot (ICD), Pepe, Athi River, Eldoret International Airport, Post Office-City Square and EMS, Kilindini Port, Mombasa, Busia Border, Malaba Border, Isebania Border, Namanga Border and Lunga Lunga Border.
- Records must be maintained for orphan medicinal substances imported, which must be made readily available for inspection by the Pharmacy and Poisons Board.

Documentation Requirements

- A formal request for importation of an orphan medicine addressed to the Registrar, PPB.
- An **original signed and stamped commercial invoice** from exporting company indicating endorsed by the pharmacist in-charge from the importing institution or any other technical person.
- For each to be imported medicinal substance, a **commercial invoice** should state the following;

• Commercial invoice reference number and date • Name and full address of both the supplier and importer. • Country of origin. • Mode of shipment (sea, air, road) • Destination port of entry (see list authorized ports of entry below) • Expected date of arrival • Trade or proprietary name of the orphan medicinal substance. • Currency used in the invoice. • Unit and total value for orphan medicinal substance. • Quantity for each orphan 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.

- Valid retention/registration certificate or listing letter issued from the Directorate of Product Evaluation and Registration if applicable.
- Valid copy of the applicant's current wholesale Dealers license from the Pharmacy and Poisons Board.
- Valid certificate of Good Manufacturing Practice from Pharmacy and Poisons Board if applicable.
- Batch certificate of Analysis issued by the manufacturer as evidence of conformity with the specifications.
- Please note that an additional special permit will be required for controlled substances as prescribed by the PPB and applicable treaty obligations.

Process steps

- Authorized importer intending to import an orphan medicinal substance shall apply using the online system.
- The application shall be accompanied by the required documentation stated above.
- Online notification to PPB personnel.
- PPB personnel will scrutinize to verify whether the requirements stated above have been fulfilled.
    - Medicinal substances that meet the above criteria will be approved as per published service charter timelines.
    - Medicinal substances that do not meeting the above criteria will be rejected with the reason(s) for rejection being stated clearly.
        - The 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 starts when PPB requests for clarification or additional information with regard to the application.
- Physical verification of consignment after approval at the port of entry.
- Final release of consignment to the applicant.

Importer Obligations for Orphan Medicinal Substances

- **Understand of Supplier of Orphan medicinal substance:**
    - Importer must declare their supplier, location, and contacts of each of orphan medicinal substance imported to Pharmacy and Poisons Board.
    - **Full responsibility** of quality, efficacy, safety, potency, and security of orphan medicinal substance lies on the importer.

- **Compliance with Good Distribution Practice (GDP) standards.**
    - Importer must ensure that the storage conditions, GDP and GMP are observed during transport and distribution, e.g. cold chain requirements.
    - Importer must have standard operating procedures (SOPs) for GDP and must comply with Pharmacy and Poisons Board guidelines on GDP.
    - Importer is responsible for recall and destruction of their orphan medicinal substance(s) imported incase of quality, safety or efficacy issues as per Pharmacy and Poisons Board guidelines. Importers of orphan medicinal substance must maintain proper records, including:
- **Record Maintenance:**
    - Importer must track all batches imported in the market and must have documented recall and pharmacovigilance procedures.
        - Quantity of orphan medicinal substance imported
        - Date of importation of the orphan medicinal substance
        - Name and address of the health facility for which the orphan medicinal substance distributed.

- Ensure supply chain integrity downstream to the health facility.
  - Importer must maintain records of all batches imported either in file or electronically that should available for audit by the Pharmacy and Poisons Board.
  - Importer must submit to the Board all the batches of orphan medicinal substance imported every quarter.
  - Importer must reporting of adverse drug reactions (ADR), quality, safety, efficacy issues to Pharmacy and Poisons Board

References/Bibliography

1. *Lee D. K. & Wong B. 2014. An Orphan Drug Framework (ODF) for Canada, Journal Population Therapeutics Clinical Pharmacology Vol 21(1):e42-e46; February 23, 2014*
2. *USFDA Orphan Drug Regulations, 2013*

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
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