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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES FOR DONATION OF HEALTH PRODUCTS AND TECHNOLOGIES

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For clarifications, comments, or suggestions, please contact:

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ABBREVIATIONS AND ACRONYMS

GMP Good Manufacturing Practice
HPTs Health Products and Technologies
IVD- In-Vitro Diagnostic Medical devices
ISO International Standards Organization
INN International Non-Proprietary Name
MD Medical device
WHO World Health Organization

DEFINITION OF TERMS

Health products includes human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products

Health technologies means the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve the quality of life

Essential medicine means medicine that satisfies the priority health care needs of the population and is selected with due regard to disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness.

Health establishment means the whole or part of a public or private institution, facility, building, or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services.

In vitro diagnostic (IVD) means an IVD as defined in the Health Act 2017.

Medicine means medicine as defined in the Health Act 2017.

Medical Device means a medical device as defined in the Health Act 2017.

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1. INTRODUCTION

1.1 Background

This guideline aims to offer overarching principles and aspects toward quality assurance of and management of HPT donations into the Kenyan territory. There are several situations that warrant the donation of HPTs. This includes: during pandemic and epidemic situations, disaster and emergency situations, donations by development partners, and Aid by other Governments towards various projects and programs of National and County interest, among others. The donations may be direct to Public health facilities and or private health establishments or faith-based health establishments.

1.2 Legal Framework/Responsibility for Implementation

The Board is mandated by CAP 244 Laws of Kenya to provide the regulatory oversight of all HPT's circulating within the Kenyan territory. This is through regulation of imports and exports under section 3b 2b of the Act and section 44 subsection 1 (ff) of the Act.

The Board shall grant or withdraw marketing authorization for medical products subject to appropriate conditions and revise such conditions for marketing authorization as necessary.It shall also grant or withdraw licenses to manufacturers, wholesalers, retailers,importers, exporters and distributors;

1.3 Scope

The Board in its mandate under section 3(b), ensures that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality, safety and efficacy. Therefore, this guideline serves to offer quality assurance principles on HPTs imported or donated by well-wishers into Kenyan territory.

1.4 Principles on Donation of HPT's

The guideline is based on the following principles namely:

1.4.1 The donation of a HPTs shall benefit the recipient of the donation and the clients/patients shall be served to the maximum extent possible;

1.4.2 A donation shall be given with full respect of the wishes and desires of the recipient organization and without violation of provisions of the Pharmacy and Poisons Act on quality, safety, efficacy and performance of HPT's. For example, if the quality, safety, efficacy or performance of an item is unacceptable in the country from which it originates, it shall be deemed unacceptable as a donation into Kenya;

1.4.3 Donations may include products which have market authorization in Kenya or those without market authorization;

1.4.4 Donations must not be sent into Kenya unannounced. At all times, there shall be sufficient communication that is understood by all parties involved in the donation process. Where needed, the Ministry of Health, its agencies, programs, Counties as well as the Pharmacy and Poisons Board may be consulted to offer any technical guidance;

1.4.5 Medicines that have been issued to patients and there after returned to a pharmacy or other health establishment as well as decommissioned medical equipment shall not be accepted as donated HPTs;

1.4.6 In certain circumstances and in accordance with applicable legislation and guidelines, the re-use of medical devices may be considered.

2. DONATION OF HPTs

a. Donations of HPTs shall be based on expressed health needs of Kenyan health establishments.

b. It is the responsibility of the recipient health establishment to specify

its needs to prevent unsolicited donations and those which may arrive unannounced and unwanted.

c. The presentation, strength and formulation (where applicable) of HPT's to be donated shall be notified to the Board.

d. ALL HPT's supplied as donations shall comply with all regulatory requirements on safety, quality, efficacy or performance in their Country of origin.

e. All HPT's to be donated into the Country must be authorized by the Board.

f. HPTs being donated into the country need not to be registered locally but their quality attributes in respect to quality, safety, efficacy and performance must be demonstratable, verifiable and traceable.

   It shall be the responsibility of the recipient health establishment in Kenya to ensure that this is provided when called upon by the Board.

g. Note that if the HPT(s) is registered in Kenya, the applicant shall attach a Letter of No Objection from the Marketing Authorization Holder or Local Technical Representative allowing import of the donation.

3. APPLICATION AND REQUIREMENTS FOR AUTHORIZATION FOR DONATED HPT'S

a) Application for donations shall be done on the portal accesible on PPB website.

b) The applications shall undergo assessment for approval of the donated health products by the Department of Product Evaluation and Registration before the donation Marketing Control can be issued by the Export and Import Unit.

c) The receiving entity in Kenya shall apply for import license from the Pharmacy and Poisons Board through the KRA iCMS system (generation of base Document) and Kentrade system.

3.1 Requirements for a donation application

a) Product Labeling must be in an appropriate language, English or Kiswahili and should adhere to the specific labeling requirements by the prescribed guideline (PPB/HPT/PER/GUD/016);
b) The donated medicines must comply with quality standards of the donor country and Kenya. WHO-GMP certification and manufacturing licenses issued by the Competent Authority in the Country of Origin should be provided;
c) The remaining shelf life should be at least 75% of the approved shelf life;
d) No expired product or medical device shall be shipped to Kenyan Market.
e) HPTs with less than 75% remaining shelf-life to expiration can be donated with Pharmacy and Poisons Boards's approval, provided the Distributing Partner is aware of the product or medical device expiry prior to the donation, and there is an agreement between the Donor and Distributing Partner that the product or medical device can be utilized. Country-specific expiry guidelines shall always be followed, unless approval per the above has been obtained;
f) The product's generic name should appear on all packaging and shipping documents, along with other relevant information e.g. quantity, expiration date, lot and control numbers, and storage/temperature requirements;
g) The source of the medicine must be declared;
h) Prior Consent Letter from the recipient specifying their needs and relevance to the disease pattern in the country (This may be waived in acute emergencies);
i) The presentation, formulation and strength of the donated drugs should aligned to the Kenyan registration requirements and standards;
j) Professional free samples shall not be considered as donations;
k) The HPTs donations must be packed in accordance with all international shipping requirements. Each shipment should be accompanied by a detailed packing list;

l) HPTs requiring special storage conditions or handling shall be clearly labeled as appropriate with temperature requirements or “Fragile,” as needed. Temperature controlled products should be considered for separate shipping from other products.

m) Maintenance of temperature protection shall be confirmed and documented. If data loggers are included in the packaging, there should be prior agreement between the Company, donor and Distributing Partners regarding how and when they are to be read and analyzed, and the actions taken if there is an excursion. Clear instructions regarding those expectations should be included with the control thermometers;

n) The expiry date should be clearly labeled on all primary and secondary packaging;

o) The following documentation shall accompany the donated HPTs;

1) A certificate of donation (from the donor) should accompany the medical product;

2) Certificate of pharmaceutical product of individual Medicine from the country of origin/ Free sale certificate from country of origin(where applicable);

3) Artworks or scanned copies of the secondary and primary packaging showing the name of product, strength, name, and address of the manufacturer and expiry dates, where applicable;

4) Summary Product characteristics;

5) Patient information leaflet;

6) Certificate of analysis from the Finished product manufacturer

7) Where vaccines are being donated, lot release certificates from origin jurisdiction and lot release protocol from the manufacturer shall be provided.

3.2 In addition, documentations for donation of Medical Devices and IVDs shall include:

a) Certificate of Free Sale confirming evidence that the medical device and/or IVD is legally sold or distributed in the open market, freely without restriction, and approved by the National competent

authority in the Country of Origin;

b) Evidence of ISO 13485:2016 certification of the original manufacturer for each medical device and/or IVD;
c) Copy of Instructions for Use for each medical device;
d) Appropriate labeling and packaging of each medical device;
e) Evidence of ISO 13485:2016 certification of the original manufacturer for each medical device and/or IVD and
f) Quality statement from the donor.

3.3 Mandatory attachments to the Donation Applications for Medicines.

a) Cover Letter.
b) Proforma invoice including Expiry dates
c) Detailed Packing List
d) Registration Certificate/ Free sale certificates/ CoPP/ Emergency Use Authorization.
e) Certificate of donation.
f) Artworks or scanned copies of the secondary and primary packaging
g) Certificate of analysis from the Finished product manufacturer
h) Summary Product characteristics.
i) Consent Letter from the recipient specifying their needs and relevance to the disease pattern in the country (This may be waived in acute emergencies).
j) If the product(s) is registered in Kenya, the applicant shall attach a Letter of No Objection from the Marketing Authorization Holder or Local Technical Representative allowing import of the donation.

4. TRANSPORT AND LOGISTICS

All donated HPTs shall be packed and transported in accordance with guidelines of good distribution practice.

5. PRESENTATION PACKAGING AND LABELING

a) All HPTs shall be in the National Language.

b) All drug donations shall be packed in accordance with international shipping regulations, and shall be accompanied by a detailed packing list, which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions.

c) The weight per carton must not exceed 50 kilograms.

d) Drugs shall not be mixed with other supplies in the same carton.

6. REFERENCES

a. *The World Health Organization: Guidelines on donated Medicines*

b. *The World Health Organization: Medicine device donations: considerations for solicitation and provision*

c. *The World Health Organization: Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices, 2017*

d. *Ministry of Health Kenya: National Guidelines on Donations of Drugs and Medical Supplies 2011*

e. *PQMD's Guidelines for Quality Medical Donations*

7. Revision History

Revision No:	Date	Author	Section(s) revised	Description of change
1.0	14/07/2022	QAO	5.0 (g)	Included sub section (g) on the letter of no objection
			6.1	Requirement for donation application of medicines.
			6.2	Donation of medical Devices and IVDs:
			7.0	Application attachments
			9.0	Presentation of packaging and labeling
			10	PQMD's Guidelines for Quality Medical Donations

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