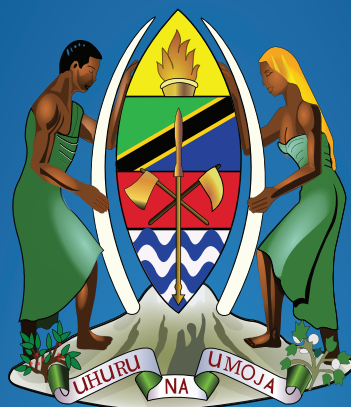


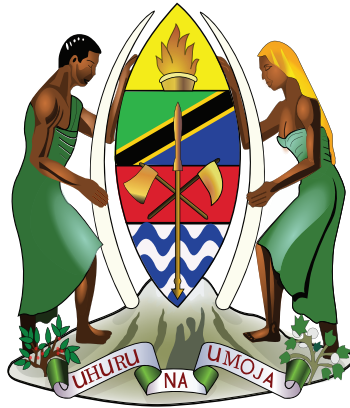
THE UNITED REPUBLIC OF TANZANIA



MINISTRY OF HEALTH

# **HEALTH COMMODITIES DONATION GUIDELINES**

**2<sup>ND</sup> EDITION 2022**



**THE UNITED REPUBLIC OF TANZANIA**  
MINISTRY OF HEALTH

# **HEALTH COMMODITIES DONATION GUIDELINES**

**2<sup>ND</sup> EDITION 2022.**

# ABBREVIATIONS

<b>cGMP</b>	current Good Manufacturing Practice
<b>CSO</b>	Civil Society Organizations
<b>DED</b>	District Executive Director
<b>DMO</b>	District Medical Officer
<b>ETA</b>	Expected Time Arrival
<b>FBO</b>	Faith Based Organization
<b>GCLA</b>	Government Chemist & Laboratory Agency
<b>GHSC TA-TZ</b>	Global Health Supply Chain Technical Assistance Tanzania
<b>IHI</b>	Ifakara Health Institute
<b>INN</b>	International Non-proprietary Name
<b>MoU</b>	Memorandum of Understand
<b>MOFP</b>	Ministry of Finance and Palnning
<b>MSD</b>	Medical Stores Department
<b>MOH</b>	Ministry of Health
<b>MOFAEAC</b>	Ministry of foreign Affairs and East African Cooperation
<b>NEMLT</b>	National Essential Medicines List for Tanzania
<b>NGO</b>	Non-Governmental Organization
<b>PMO</b>	Prime Minister's Office
<b>PORALG</b>	President's office, Region Administrative and Local Government
<b>POE</b>	Point of entry
<b>RMO</b>	Regional Medical Officer
<b>TBS</b>	Tanzania Bureau of Standards
<b>TMDA</b>	Tanzania Medicines and Medical Devices Authority
<b>TRA</b>	Tanzania Revenue Authority
<b>TAEC</b>	Tanzania Atomic Energy Commission
<b>WFP</b>	World Food Programme
<b>WHO</b>	World Health Organization

# Table of Content

FOREWORD	III
ACKNOWLEDGMENT	IV
DEFINITIONS OF TERMS	V
INTRODUCTION	1
1.1 Rationale	2
1.2 Scope	2
1.3 Policies, legal and institutional framework	2
1.4 Targeted users of the guidelines	2
ROLES AND RESPONSIBILITIES (RORE) OF KEY PLAYERS	3
HEALTH COMMODITIES SELECTION, SPECIFICATION, AND DEMAND PLANNING.	6
QUALITY ASSURANCE AND REGULATIONS	7
INFORMATION & MANAGEMENT	11
GUIDANCE TO DONORS AND RECIPIENTS	13
MONITORING AND EVALUATION	15
TRANSITION PLAN AND PHASING OUT.	16
REFERENCE	17
ANNEXE 1	18
1.5 CHECKLIST FOR DONATION OF HEALTH COMMODITIES	18
ANNEXE 2	20
PROCESS FOR SOLICITING AND OFFERING DONATIONS	20
ANNEXE 3	21
MEMORANDUM OF UNDERSTANDING	21

# FORWARD

The first edition of the Guidelines for Medicines and Medical Supplies Donations for Tanzania Mainland was published in February 2015. The guidelines have been in place for the past six years and used by different actors, both government and non-government actors, donor and recipient of the donation. The ultimate goal was to strengthen the provision of health services at all levels of service provision through utilization of the donated products. Evolution of technologies on health services provision coupled with epidemics and experience in combating them, has led to the review of the guidelines and accommodate the current environment.

The prominent changes in this edition are based on the experiences and comments received through a consultative review process and implementation of the first edition. The main focus of the guideline is protecting the consumer of the donations as well as the country from inappropriate donation and therefore, enhancing the responsibility and involvement of recipients in the process of health commodities donations. It emphasizes the need for coordination in the whole process of donation and provided guidance on appropriate practices for donors and recipients towards donation processes. The guidelines provide a clear narration for health commodities donations ranging from emergency donation to long-term donations that supports the national health systems as well as individual health facilities.

The review also took into account the global experiences on different types of medicine donations with their challenges, these experiences were used as learning lessons to inform the development of this guideline. Across the globe it was revealed that, uncoordinated donations resulted to excess drugs and or expired donations in recipient countries, circulation of unregistered medicines and donations labelled in languages not understood by recipient countries. The same experiences existed in Tanzania with donations of machines whose operating systems were outdated and had required equivalent cost of a new machine to update their systems for them to be functional. Furthermore, other recipient counties incurred additional costs for the destruction of the expired drugs.

This respectable work was done in collaboration with keys stakeholders to ensure it suits the current interest for both donor and recipient. I embolden all donors and recipients from both public and private health sector who are involved in health commodities donations to use this guideline for their planning and execution of donation processes with the aim enhancing quality on health service delivery and safeguarding the lives of the people, protecting environment and avoidance of unnecessary costs which are always associated with inadequately managed donations. Tanzania welcomes the health commodities donations that meets the criteria stipulated in this donations guideline and it is committed towards efficiently utilization of these donations for improvement of health service delivery.



**Ummy Ally Mwalimu (MP)**  
Minister for Health

# ACKNOWLEDGMENT

The Ministry of Health, wishes to extend its gratitude to all who have contributed to developing these Donation Guidelines.

This Health Commodities Donation guidelines result from the efforts of many partners involved in delivering health care services in the United Republic of Tanzania. We would like to recognize and express sincere gratitude to all technical teams who participated tirelessly in preparing the Health commodities donation guidelines.

The preparation of this document was made possible through financial and technical assistance from the USAID Global Health Supply Chain Technical Assistance – Tanzania (GHSC TA -TZ).

Finally, the contributions of all stakeholders who participated in the process are acknowledged with sincere thanks.



**Prof. Abel N. Makubi**  
Permanent Secretary Ministry of Health.

# DEFINITIONS OF TERMS

**Disaster is a catastrophic event**, especially one occurring suddenly and causing great loss of life, damage, or hardship such as flood, cyclone, an eruption of pandemic diseases.

**Donation** is an act or instance of giving away health commodities to an intended recipient.

**Donor** refers to a person or organization that gives out health commodities following a request from a Government, private organization or Individual.

**Emergency** is a sudden, urgent, usually unexpected occurrence or occasion requiring immediate action.

**Equipment** A tool or device created and designed in various materials, mechanisms, shapes, sizes and styles for an accurate and specific purpose.

**Facility** is the service delivery point where donated health commodities are received and utilized.

**Health commodities** refer to pharmaceuticals, medical devices, medical supplies, medical aids, In-vitro diagnostics, Medical equipment, chemicals, and technologies.

**Individual** a person who receives or donate health commodities

**Medical devices** A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or another similar or related article intended by the manufacturer to be used, alone or in combination for a medical purpose.

**Medical supplies** refer to items for medical use that are suitable for use in a health care facility or the home and that are disposable or semi-disposable and are non-reusable.

**Pharmaceuticals** are substances used in the diagnosis, treatment, or prevention of disease and for restoring, correcting, or modifying organic functions.

**Public representatives** - Covers all persons who can represent the public interest and may include appointed members. These include Ministers, Members of the Parliament, Councilors, and village chair person who can solicit donations of health commodities in one way or another.

**Recipient** refers to Government, Private organization or Person that receives health commodities

**Unservisable Health commodities**- covers all expired, rejects, recalls, damaged, wrong items, ward stocks, and patient returned medicines

# CHAPTER ONE

## INTRODUCTION

Health commodities donation has a long history as an essential component to improving availability and access to quality affordable health services in Tanzania. Donations are received from within and/or outside of the country from private companies, Non-Governmental Organizations (NGOs), Faith-Based Organizations (FBOs), individuals, bilateral and multilateral agencies.

The intended beneficiaries of donations range from individuals, facilities, Councils, Regions and Ministries. Appropriate donation practices of Health commodities can have major advantages for both recipients and donors. Health commodity donations can be a strategic benefit for the country in supporting healthcare systems and/or ensuring health commodities access to populations. Good donation practices may provide savings in terms of budgets, enabling these resources to be used for other purposes. However, if donations are not appropriate and well-coordinated may result in undesired benefits that burden the recipient. Examples of experienced undesired benefits include donations of near to or expired Health commodities, outdated technologies, Health commodities labelled in languages not understood by the recipient.

Recognizing the value of donated health commodities and providing clarity into the donation process, the Government of Tanzania, in collaboration with various stakeholders, developed the 1st edition of guidelines for Medicines and Medical Supplies Donation for Tanzania Mainland- in February 2015. Despite using the guidelines, some issues were not adequately addressed in the first edition throughout the implementation.

To address the noted gaps, the Ministry responsible for health, in collaboration with key stakeholders, reviewed and updated the first edition based on the following core principles to provide more clarity and guidance:

1. Maximum benefit to the recipient: a health commodity donation should benefit the recipient to the maximum extent possible;
2. Respect for wishes and authority of the recipient: a donation should be given with due regard for the wishes and authority of the recipient and in conformity with existing government policies and administrative arrangements;
3. No double standards in quality: there should be no double standard in quality, however, the Tanzania regulatory authorities shall approve the donation prior to importation; and
4. Effective communication between donor and recipient: there should be effective communication between the donor and the recipient, with all donations resulting from a need expressed by the recipient. Transparent on these donations should be of paramount.



## **1.1 Rationale**

The first edition of Guidelines for Medicines and Medical Supplies Donations for Tanzania Mainland - 2015 has been implemented for almost six years. In the course of its implementation evolution of technologies, changes in government legal and policies have led to an increased demand which necessitates an effective and efficient way of managing health commodities donation to address requirements for both donors and recipients.

Therefore, these revised guidelines guide the Donor and Recipient on procedures to determine requirements/needs and quality in accordance with government standards.

## **1.2 Scope**

These guidelines cover scenarios for Health commodities emergencies and long-term donations to national health systems, facilities, and individuals from the public and private organizations.

## **1.3 Policies, legal and institutional framework**

The current National Health Policy (2007) recognizes the role of different actors in supporting government efforts to improve health service provisions in the country.

The use of these guidelines is aligned with the existing government policies, laws, and regulations, including the Public Health Act of 2009 and the Tanzania traditional and alternative Medicine Act No. 23-2002. Quality standards for donated health commodities will be guided by government legal frameworks, including Tanzania Medicines and Medical Devices Act, Cap 219 of 2019, The Standards Act, 2009 and others that will be existing in the time of effecting the donation. All imported donations should comply with the prevailing government import tax, legal and regulation arrangements.

## **1.4 Targeted users of the guidelines**

This guideline is intended for use by all players who will be involved by donated health commodities including the following: Government Ministries; Department and Agencies; Regions and Councils; International organisations; Non-Government Organisations both Local and International; Faith Based Organisation; Research and Academic institution; and media.

# CHAPTER TWO

## ROLES AND RESPONSIBILITIES (RORE) OF KEY PLAYERS

The donation of health commodities is dynamic and involves multiple players in both local and international communities. Donors and recipients are required to engage these key players directly or indirectly in the process of health commodity donations.

### 2.1 Prime Minister's Office (PMO)

- i. Coordinate and account for Health commodities donations related to emergency and disaster management.

### 2.2. Ministry responsible for Foreign Affairs

- i. Handling of International Health commodities donations/ deployment procedure
- ii. Initiate donation requests when needed
- iii. Liaise with Ministry responsible for health on the requirements and specifications for health commodities donations to the United Republic of Tanzania
- iv. Coordinate and facilitate communication of policies and plans to donors

### 2.3. Ministry responsible for health

- i. Develop, update and disseminate Health policy, including donation guidelines for health commodities.
- ii. Define product specifications and demand plans for health commodities.
- iii. Requests for health commodities donation within and or outside the country through relevant authorities
- iv. Coordinate health commodities donations/ deployment upon request from Ministry responsible for foreign affairs
- v. Collaborate with other sector ministries to monitor the implementation of the guide lines.
- vi. Safeguard quality, verification and inspection of donated health commodities.
- vii. Provision of waiver for import permit on donated health commodities
- viii. Prepare, Review and approve Memorandum of Understanding /Agreement between the recipient and the donor.
- ix. Inventory management of donated Health commodities.
- x. Monitor and evaluate adherence to the health commodities donation guidelines

## **2.4. Ministry responsible for Finance**

- i. Approval of Health commodities donation.
- ii. Approval of Financial/grants Insurance of Health commodity donations exemptions.
- iii. Approval of import/export permit for Health commodity donations.

## **2.5. Ministry responsible for Legal Affairs**

- i. Provide legal advice of Health commodities donation Memorandum of Understanding/Agreement between the recipient and the donor.

## **2.6. Ministry responsible for Regional Administration and Local Government**

- i. Adhering to the Health commodities Donation Guidelines.
- ii. Provide semi-annual reports to the Ministry responsible for Health on Health commodities donation received.
- iii. Facilitate Health commodity Donation Request.
- iv. Initiate Health commodity Donation Request.
- v. Monitor and evaluate the received health commodities used for the intended purpose.

## **2.7. Regulatory Bodies - TMDA/TBS/GCLA/TAEC/ZFDA**

- i. Issuance of Import and Export Permit.
- ii. Inspection of donated Health commodities.
- iii. Enforce compliance to quality assurance and regulations for donated health commodities.
- iv. Post-market surveillance for donated Health commodities.
- v. Inventory record of donated Health commodities.

## **2.8. Medical Stores Department**

Store and distribute Health commodities donated for public health facilities

## **2.9. Public representatives**

- i. Solicit and advocate Health commodity Donations.
- ii. Consulting technical advice before requesting or accepting any health commodity donation.
- iii. Adhering to Health commodity Donation Guidelines.

## **2.10. Donor**

- i. Adhering to the Health commodities Donation guidelines
- ii. Mutual collaboration with the Ministry responsible for health for appropriate planning of donations
- iii. Furnish information to the recipient concerning the Health commodities donation
- iv. Dispose or re-export any unwanted health commodities before recipient handling
- v. Adherence to in country's disposal guidelines

## **2.11. Recipient**

- i. Adhering to the Health commodities Donation guidelines
- ii. Provide semi-annual reports to the Ministry
- iii. Responsible for Health on Health commodities donation received.
- iv. Initiate Health commodity Donation Request.
- v. Monitor and evaluate the received health commodities used for intended purposes

# CHAPTER THREE

## **HEALTH COMMODITIES SELECTION, SPECIFICATION, AND DEMAND PLANNING.**

All health commodities donations must be based on an expressed need and be relevant to the disease pattern in the United Republic of Tanzania. Their selection, quantities, specifications, technology, safety & quality must be agreed upon in the MoU (Annex 3) between donor and recipient before shipping/delivery of a donation consignment. In case donated health commodities do not fit the recipient's requirements, they shall be rejected.

- a) Health commodity donations to specific health facilities shall be endorsed by the respective accounting officers who are the: Permanent Secretary (PS), Regional Administrative Secretary (RAS) and District Executive Director (DED).
- b) Donated Health commodities shall be in line with the latest version of Tanzania laws, regulations and guidelines.
- c) Both donor and recipient must adhere to the agreed supply plan for Health commodities donated.

### **Justifications and Explanations**

The provision stresses that it is a prime responsibility of the recipient to select, specify and determine needs for Health commodities. It is intended to prevent unsolicited donations to health facilities that may arrive unannounced and lead to a pile of unwanted health commodities with a possible impact on the environment.

The provision of the Supply plan gives clarity on the Expected Time of Arrival (ETA) to avoid disruption of the Supply chain system.

# CHAPTER FOUR

## QUALITY ASSURANCE AND REGULATIONS

Donated health commodities have to originate from a reliable source and comply with quality standards in the donor country and the United Republic of Tanzania. The WHO "Certification Scheme on the Quality of Pharmaceutical Products" moving in international commerce should be used, including relevant batch certificates. The respective regulatory authorities must register donated Health commodities. In the exceptional cases where this is not possible, donated health commodities must be cleared by the Tanzania Medicine and Medical Devices Authority (TMDA) before they can be imported or released for distribution.

### Justifications and explanations

This provision prevents double standard: Health commodities of an unacceptable quality in the donor country should not be donated to other countries. Donated health commodities should be authorized for sale in the country of origin and manufactured following international standards of current Good Manufacturing Practice (c GMP).

In addition, medicines and medical devices must be registered by TMDA. TMDA registration processes also ensure that product labelling is appropriate for the national context and

### Possible exceptions:

- i) In case the WHO Certification Scheme is not applicable, the donor should give a justification. However, the Ministry responsible for health shall endorse mechanisms for a waiver that can be applied.
- ii) When donors provide funds to purchase locally registered health commodities from Tanzania producers, the WHO Certification Scheme requirement does not apply.

Requirement on the donated products:

- a) List of donated health commodities must include the product's name, manufacturer's name, site and country of origin. These documents must be sent to the recipient early to ease importation and clearance processes.
- b) The language should be in Swahili and/or English; in case there is any other language, a certified translation version from the manufacturer shall be provided.
- c) All medicinal health commodities must be labelled in the English language, Swahili or a certified translation version from the manufacturer; the label on each container should at least contain the international non-proprietary name (INN) or generic name, and the following

- i. Batch number,
- ii. Dosage form,
- iii. Strength of the medicines,
- iv. Name of manufacturer,
- v. Quantity in the container/bottle or box,
- vi. Storage conditions,
- vii. Date of manufacture and,
- viii. Expiry date, as clear dates, not codes.
- ix. Prescriber information for all medicines.

For health commodities other than medicines, the labelling shall include the following;

- i. Name of health commodity;
- ii. Identifier of health commodity
- iii. Family of the health commodity;
- iv. Batch or lot number;
- v. Name, physical address and contacts of the manufacturer;
- vi. Content, size, length, weight or number of units
- vii. Indication of sterility status (if applicable)
- viii. Indication whether it is New/Used/Refurbished – including duration or number of cycles of previous use where applicable
- ix. Storage conditions
- x. Date of manufacture (month/year)
- xi. Expiry date/life span (if applicable)
- xii. Words for single use only (if applicable)
- xiii. Direction for use

d) Respective regulatory authorities shall register donated health commodities; in the exceptional cases where this is not possible, donated items must be endorsed by the Ministry responsible for health and cleared by regulatory authorities before they can be released for consumption.

e) No health commodities should be donated that have been issued to patients and then returned to pharmacies or elsewhere or were given to health professionals as free samples.

## Justifications and Explanations

Patients return unused medicines to a pharmacy to ensure their safe disposal; the same applies to medicine samples that health workers have received. In Tanzania, the re-issue of medicines is not permitted because their quality cannot be guaranteed. It is for this reason that returned medications should not be donated. In addition to quality considerations, returned medicines are difficult to manage at the receiving end because of broken packages and small quantities.

f) The consignment that has not been cleared at the Point of Entries (POE) and proved to be unwanted shall be re-exported or disposed of within the country at the Donors costs.

g) After arrival in the United Republic of Tanzania, all medicines should have a remaining shelf life of greater than 80% for products with a product shelf life of more than two (2) years; and greater than 60% for products with production shelf life less than two (2) years.

h) For health commodities (other than medicines), where applicable, should have a remaining shelf-life/life span of not less than 60% of the original shelf-life/life span.

Possible exceptions:

i. For Health commodities that are manufactured with a short shelf-life of less than two years because of their physical properties.

ii. Health commodities donated directly to specific health facilities, Regional Administrative Secretary (RAS) / District Executive Director (DED) and Permanent Secretary (PS-Health) must be notified on their quality (i.e. the quantity and remaining shelf-life) for an acknowledgement before shipping.

iii. In all cases, the date of arrival and the expiry dates of Health commodities must be communicated well to the recipients in advance.

i) For used Health commodities, they must be refurbished and tested, all essential parts, accessories and working materials be included with relevant supporting documents indicating items are in good order and submitted before shipment

j) For donated Health commodities with special storage requirements, the donor shall pre-notify the recipient for proper transport, storage and quick clearance from the point of entry.

### **Possible exceptions:**

Vaccines demand stringent conditions during storage and distribution. Therefore, it should only be donated in close collaboration with the Ministry responsible for Health matters in the United Republic of Tanzania.



# CHAPTER FIVE

## **INFORMATION & MANAGEMENT**

- a) The United Republic of Tanzania, through the Permanent Secretary responsible for health, must be officially informed on all Health commodities donations.
- b) Health commodities donations to specific health facilities require prior notification to the Permanent Secretary/Regional Administrative Secretary (RAS)/District Executive Director (DED) before shipping the consignment by the donor.

NB: -There must be a signed agreement between the Recipient and Donor, whether local or international, before Health commodities are donated.

## **Justifications and Explanations**

Many health commodities donations arrive unannounced. Detailed advance information on all donations is essential to enable the United Republic of Tanzania to plan for the receipt and coordinate the donations with other sources of supply. This provision is needed in the United Republic of Tanzania to prevent health commodities from being priced according to the retail price of the product in the donor country, which may lead to elevated overhead costs for import tax, clearance, and handling.

NB: -The declared value of Health commodities donation should be based on its generic equivalent's wholesale world-market price.

## **Possible exception**

In the case of patented medicines (for which there is no generic equivalent), the wholesale price of the nearest therapeutic equivalent could be taken as a reference.

- c) The cost associated with the donation, whether local or international, should be paid by the donor unless expressly agreed otherwise with the United Republic of Tanzania in advance. Such costs may include but are not limited to warehousing, port clearance, quality testing and appropriate storage and handling.
- d) The cost of disposing of/re-exportation of unwanted Health commodities should be borne by the donor unless specifically agreed otherwise with the United Republic of Tanzania in advance. Donors are requested to fill the donation form (Annexe 1) annexed with these guidelines before shipping goods and submit it to the Ministry responsible for health.

## **Justifications and explanations**

These incidental costs can be quite prohibitive and erode the MoHCDGEC budget. On the other hand, if the donor makes provisions for these costs, the benefits of the donation will be maximized.

- e) Health commodities donations reports from Councils, Regions and Ministries shall be submitted to the Ministry responsible for health.

## **Justifications and explanations**

This ensures smooth flow of information from Councils and Regional to Central level for Health commodities donations inventory management.

# CHAPTER SIX

## GUIDANCE TO DONORS AND RECIPIENTS

### A) Guidance to Donors

Before a decision is made for Health commodities donation, consider the following;

- a) Request for guidance and express intention for donating Health commodities to the recipient.
- b) Request for the Health commodities donation guidelines in place.
- c) Request for the list and quantities of the health commodities needed by the recipient.
- d) Check for national regulations about Health commodities.
- e) Plan for Health commodity donation based on established needs by the recipient
- f) Consult with the relevant Ministry/Authority for any exceptional or special documentation requirements.
- g) Inform the recipient of Health commodities consignment before shipment.
- h) Agree in advance on the management of unserviceable/unwanted health commodities.
- i) Decide in advance on a system in place for collecting and processing complaints.

2. Donation in cash is in accordance with the laws governing financial regulation at the Ministry responsible for Finance. Exceptions in the case of emergencies/disasters, as this follows the Disaster Management Act, 2015 under the Prime Minister's Office (PMO)

### B) Guidance to the recipients

- a) Provide potential donors with clear and comprehensive information on Health commodities donation
- b) Define the kind of assistance in Health commodities required
- c) Establish demands for Health commodities to be donated (i.e. Identification, selection, specifications, forecast and supply plan)
- d) Define the minimum remaining shelf-life/ life span for Health commodities.
- e) Define quality standards for Health commodities
- f) Validate documentation before receipt and regulate on Quality of Health commodities donated
- g) Determine capacity to handle Health commodities (i.e. Infrastructures, Storage space, Cold chain system, transportation, Recourses etc.)
- h) Verify Health commodities donation documents at delivery points (i.e. Import permit, Regulatory board clearance certificates etc.)

- i) Maintain Health commodities donation Inventory management.

### **Justifications and explanations**

Recipients should be clear as to the minimum remaining shelf-life/life span that is appropriate, as specified in respective government guidelines.

Recipient through Regulatory authorities shall confiscate and dispose of Health commodities donations if deemed necessary. (Donations originating from Local markets)

# CHAPTER SEVEN

## MONITORING AND EVALUATION

Monitoring and Evaluation of the appropriateness of health commodities donations is an absolute necessity that determines the effectiveness, efficiency and adequacy of current and future donations. Thus collection, consolidation and analysis of these data lead to informed decisions for Health commodities management.

The following are key areas to measure effectiveness, efficiency and adequacy of health commodities donation;

- i. The recipient should do a cost-benefit analysis to help determine the donation's usefulness for the donor and the recipient.
- ii. Long-term donation programs should be evaluated and verified at Point of Entry (POE) and periodically checked for usefulness.
- iii. In emergencies, the appropriateness of the health commodities should be monitored and evaluated as part of the Evaluation of the disaster response.
- iv. The Ministry responsible for health and relevant authorities should maintain a data base for Donated Health commodities to facilitate proper management and promote transparency and responsibility.
- v. The recipient should periodically review and update the Inventory of donated Health commodities.
- vi. The recipient should do the annual assessment on the adherence to Health commodities donation guidelines.

# CHAPTER EIGHT

## **TRANSITION PLAN AND PHASING OUT.**

The MoH and the Donor shall set the Phasing out protocol of the said product or technology and anticipate the cost.

If the donation require the Government to continue delivering of the service even after the Donor has phased out, a plan to mitigate the cost must be in place. The Government will be notified 24 Months prior to a complete withdraw of the support. If the commodities become unservisable during the transition period, the Donor will carry out the disposal process according to the existing regulations and Guidelines.

## REFERENCE

1. Guidelines for Medicines and Medical Supplies Donations for Tanzania Main land-2015
2. The Public Health Act of 2009.
3. The Tanzania Traditional and Alternative Medicine Act No. 23-2002.
4. Tanzania Medicines and Medical Devices Act, Cap 219 of 2019.
5. The Standards Act, 2009, Pharmaceuticals and Poisons Act of 197.

# ANNEXE 1

## MINISTRY OF HEALTH

### 1.5 CHECKLIST FOR DONATION OF HEALTH COMMODITIES

Name of the Donor: .....

Contacts: .....

Physical address: .....

#### A. Check/Tick as appropriate:

Sno.	Communication, Coordination & Collaboration	YES	NO	Remarks
1.	Has an official request for the donation been made?			
2.	Does donation of Health commodities reflect recipient needs?			
3.	Has an official agreement between Donor and Recipient been made?			
4.	Do the demands/specifications for health commodities provided by the recipient?			
5.	Is there any anticipated benefit from donation?			
6.	Do the Health commodities donated adhere to respective guidelines?			

#### B. Check/Tick as appropriate

Sn.	Costs	Donor	Recipient	Remark
1.	Import/Export duties			
2.	Customs Clearing Charges			
3.	Direct delivery to MSD/respective entity			
4.	Installation of equipment			
5.	Training of user department (user&Services)			
6.	Maintenance/Supporting services			
7.	Recall/disposal of donated Health commodities as per respective guidelines (should requirements not be met)			

Sno.	Essential Documents to be submitted/Attached before shipment	Yes	No	Remark
1	Letter of support from donor			
2.	Donation Certificate			
3.	Donor/Recipients Agreement (MOU)			
4.	Invoice			
5.	Certificate of Origin			
6.	Certificate of Analysis/Conformity /Standards			
7.	Air way Bill/Bill of Lading			
8.	Parking List			

**D) Name of the recipient.....**

Contacts:.....

Physical address:.....

**E) Name of the applicant:.....**

Contacts:.....

Physical address:.....

Signature:.....

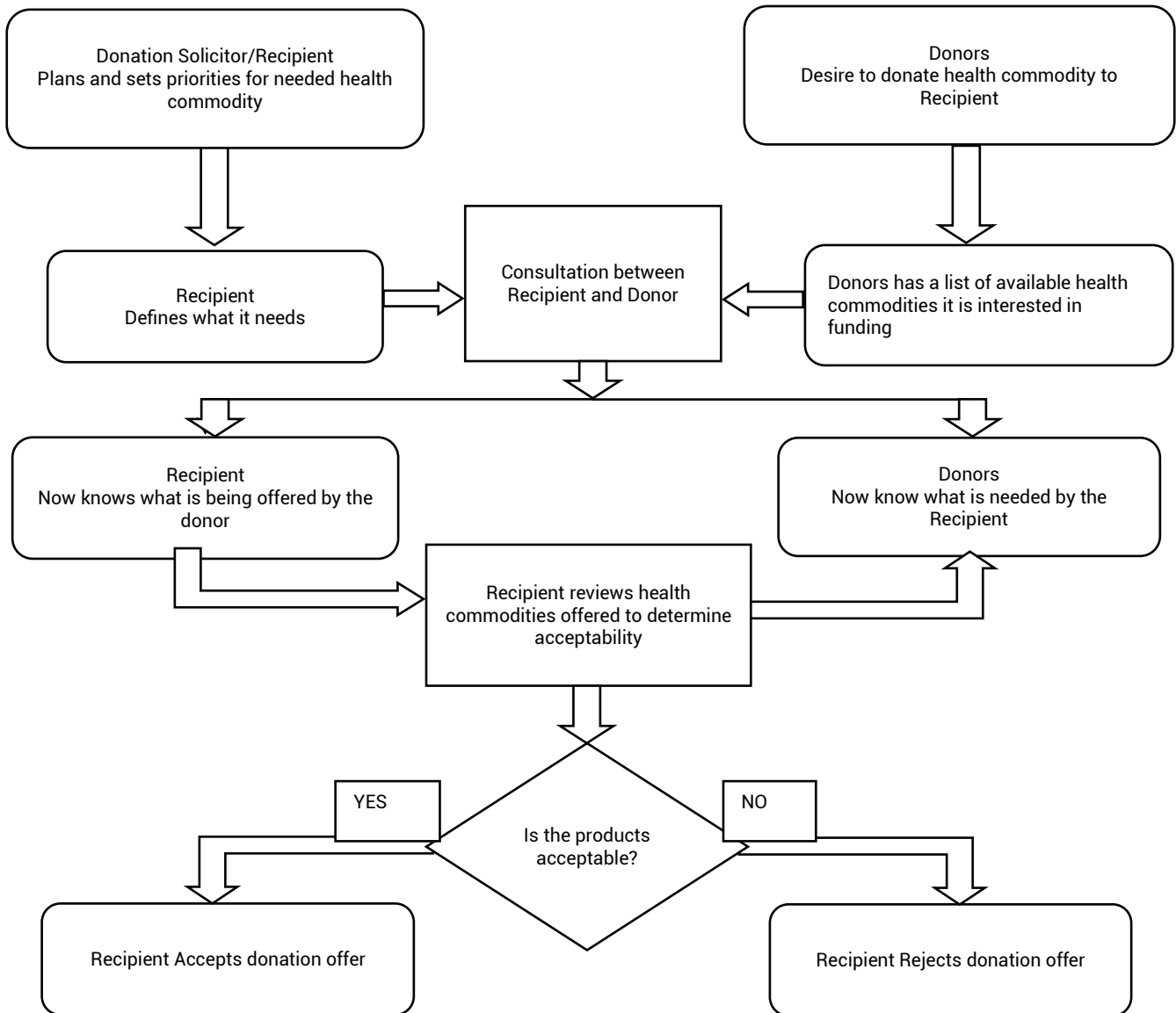
(Please submit the completed form(s) to Permanent Secretary

(Ministry responsible for health before shipment)



## ANNEXE 2

### PROCESS FOR SOLICITING AND OFFERING DONATIONS



## ANNEXE 3

### MEMORANDUM OF UNDERSTANDING

Between the

.....

(Hereinafter referred to as "Recipient")

And

.....

(Hereinafter referred to as "Donor")

#### Introduction

1.1 The Donation Agreement (hereinafter referred to as the "Memorandum of Understanding") governs the donation to be made by the donor to the recipient in support of the recipient's requirements as ..... (Reason for donation). The donation is to be used solely for humanitarian purposes, and the recipient is free to decide how best to use the donated health commodities to combat .....

1.2 This Memorandum of Understanding outlines the roles and responsibilities of the Recipient and the Donor under this agreement.

#### Donation

1.3 The Donor agrees to donate to the Recipient..... (collectively, referred to as the "Donation").

1.4 The quantity of the delivered .....has a total value (total purchase price of the donor not including VAT) of .....as further detailed in the invoice provided.

#### Delivery and Ownership

1.5 The donation shall be transported by .....(logistic company) (hereinafter referred to as freight forwarder), contracted by the donor, as a freight forwarder in .....(Country of origin), responsible for the transport to Tanzania, and with a freight forwarder specified and contracted by the recipient for the in-country transport.

1.6 The donor will then organize the customs clearance through .....(clearing and forwarding agent in Tanzania). The donor will carry any import duties that may arise in the country during the donation's arrival.

1.7 The donation of .....(donated items) shall become the property of the recipient at the

point of pick-up, agreed upon by both parties.

Once the donation has been handed over, it is the property of the recipient. After delivery, the recipient shall be responsible for proper handling, in-country transportation and storage of the donation. Further distribution to hospitals, etc., is at the Recipients' discretion.

1.8 The recipient shall arrange and organize the transport and delivery to the final recipients of the products - hospitals and health structures - within Tanzania and be responsible for handover protocols with these final recipients. Documentation of final handover protocols will be made available and communicated to the donor end of the in-country delivery process.

#### Warranties, Responsibility, and Recommendation

#### Primary Contacts

The Donor and Recipient shall each nominate an official as the primary contact person to coordinate all issues related to this MoU. As of the time of signature, the primary contacts are listed below.

<b><u>Donor:</u></b>	<b><u>Recipient:</u></b>
.....	.....
<b>Represented in the country by</b>	<b>Represented by</b>
<b>Contact:</b>	<b>Contact:</b>

1.9 A party may change its primary contact person(s), in which case the new primary contact person(s) shall be communicated to the other party in writing.

#### General Provisions

1.10 For the purposes of this MoU, each party is an independent contractor and not the joint venture, agent or employee of the other party. Neither party shall have authority to make any statements, representations, or commitments of any kind, or to take any action which shall be binding on the other party, except as may be explicitly provided for in this MoU or authorized in writing by the other party.

1.11 Amendments to this MoU must be in writing and agreed upon by both parties through an exchange of letters.

1.12 Any termination of this agreement is subject to prior written notice and the orderly conclusion of any ongoing activities.

1.13 Any matter relating to the interpretation or the execution of this MoU which is not covered by its terms shall be resolved by reference to the laws of the.....(country) For the avoidance of doubt, the United Nations Convention on Contracts for the International Sale of Goods (dated April 11, 1980) does not apply to this agreement. Any dispute relating to this agreement's interpretation or application shall be subject to conciliation unless amicably settled. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed

upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce, Paris. The parties shall accept the arbitral award as final.

Accepted on behalf of the final recipients of the ..... Accepted on  
behalf of .....**(donor)**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date



World Health  
Organization