

UNITED REPUBLIC OF TANZANIA

Ministry of Health and
Social Welfare



GUIDELINES FOR MEDICINES AND MEDICAL SUPPLIES DONATIONS FOR TANZANIA MAINLAND

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ABBREVIATIONS

GMP	Good Manufacturing Practise
TFDA	Tanzania Food and Drugs Authority
DED	District Executive Director
DMO	District Medical Officer
MSD	Medical Stores Department
MOHSW	Ministry of Health and Social Welfare
RMO	Regional Medical Officer
NEMLIT	National Essential Medicines List for Tanzania
WHO	World Health Organisation

FOREWORD

Donations, if appropriate and well planned, can provide valued assistance in supporting the existing health care services of a government facing ever increasing burden of financing the health needs of the country with limited resources. The Government of Tanzania has policies and institutional arrangements in the health sector that promote alignment of financial assistance with the sector priorities, and harmonisation among development partners in their support for the provision of a national essential health interventions package. These arrangements address provision of essential medicines and health commodities that are required for the package of services.

Tanzania has benefited in the past from various medicine donations that have complemented national systems for health care provision, and it is hoped that this will continue. On many occasions Tanzania has had to meet considerable unexpected expenditure to process donations that had not been properly planned. Donations may also have unwanted effects on existing institutional arrangements in the country's financing, procurement and supply chain management systems.

Unlike financial assistance, in-kind donations may bring particular challenges in terms of compliance with national medicines regulations. To ensure that donations are indeed useful and fully utilized, these guidelines have been prepared in line with those published by the World Health Organisation (WHO), with some modifications to suit the specific needs of Tanzania.

These guidelines are directed not only to potential medicine donors, but also to all persons and organizations that may solicit medicine donations and were developed primarily to ensure that all donations meet the express needs of recipients in Tanzania.

Each article in the Guidelines has been combined with the respective justifications, explanations and possible exceptions for easy referencing. All stakeholders are urged to familiarize themselves with, and follow these guidelines.

I am sure that this will avoid the occasional unpleasant decisions we have had to make in the past. Choosing to either accept the donation or destroy it, or refuse and give offence to willing supporters of our health care system.

Please ensure that these guidelines are followed precisely to build on our good international relations.



Dr. Seif S. Rashid

HON. MINISTER FOR HEALTH AND SOCIAL WELFARE.

1.0 SELECTION OF MEDICINES

- a) All medicines and medical supplies donations must be based on an expressed need and be relevant to the disease pattern in Tanzania mainland. Except in acute emergencies, medicines and medical supplies should not be sent without prior clearance by the Ministry of Health and Social Welfare.
- b) Donations to specific primary health facilities may only be received at that level on the express written authority from the higher levels: Regional Medical Officer/District Medical Officer. In all cases it is important that the donation be cleared and approved well in advance before being communicated to the recipients.

Justifications and Explanations

The provision stresses the point that it is the prime responsibility of the recipients to specify their needs. It is intended to prevent unsolicited donations, and donations which arrive unannounced and unwanted. It also empowers the recipients to refuse unwanted gifts and donations.

Possible exceptions: in acute emergencies the need for prior clearance by the recipient may be waived, provided the medicines are included in the World Health Organisation list of essential medicines for use in acute emergencies (2006) or latest.

- c) All donated medicines must appear in the latest version of the National Essential Medicines List for Tanzania Mainland (NEMLIT).

Justifications and explanations

This provision is intended to ensure that medicine donations comply with the Tanzania mainland National Medicine Policy and the national essential medicines list. These guidelines aim at maximising the positive impact of the donation, and prevent the donation of medicines which are unnecessary and/or unknown in Tanzania mainland.

Possible exceptions: an exception can be made for medicines needed in sudden outbreaks of uncommon or newly emerging diseases; as such medicines may not be registered in Tanzania mainland. Exceptions can also be made on the basis of a specific request to the Government of the United Republic of Tanzania.

- d) The dosage form, strength and formulation of donated medicines, should be similar to those commonly used in Tanzania mainland.

Justifications and exceptions

The staffs working at different health care levels in Tanzania mainland has been trained to use a certain formulation and dosage schedule and cannot constantly change their treatment guidelines. Dosage calculations based on unusual formulations may result in medications errors.

2.0 QUALITY ASSURANCE AND SHELF LIFE

- a) All donated medicines have to originate from a reliable source and comply with quality standards in both 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, and relevant batch-certificates included, all donated medicines must be registered by the Tanzania Food and Drug Authority (TFDA). In the exceptional cases where this is not possible, donated medicines must be cleared by the TFDA, before they can be released for distribution.

Justifications and explanations

This provision prevents double standards: medicines of an unacceptable quality in the donor country should not be donated to other countries. Donated medicines should be authorised for sale in the country of origin, and manufactured in accordance with international standards of current Good Manufacturing Practice (cGMP). TFDA registration processes also ensure that product labelling is appropriate for the national context and standard treatment guidelines.

Possible exceptions: in acute emergencies the use of the WHO Certification Scheme may not be practical; however if it is not used, a justification should be given by donor. When donors provide funds to purchase locally registered medicines from Tanzania producers, the requirement does not apply.

- b) No medicines should be donated that have been issued to patients and then returned to a pharmacy, 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 have been received by health workers, In Tanzania the re-issue of medicines is not permitted because their quality cannot be guaranteed. It is for this reason that returned medicines should not be donated. In addition to quality considerations, returned medicines are very difficult to manage at the receiving end because of broken packages and small quantities involved.

Possible exceptions: an exception can be for large quantities of unused medicines, such as from the army stocks, provided they are packed in their original containers and the quality is assured, or for very expensive medicines for particular patients. In such cases seek clearance from the MoHSW and TFDA.

- c) After arrival in Tanzania mainland all donated medicines should have a remaining shelf-life of at least one year.

Justifications and explanations

Under emergency situations, there may be logistical problems limiting immediate distribution. Distribution through different storage levels (e.g. central MSD, zonal MSD and health facilities) may take up to six to nine months. This provision prevents donations of medicines near their expiry date which could reach the patient after expiry.

Possible exceptions: possible exceptions are those medicines which because of their physical properties, are manufactured with a short shelf-life of less than two years. Vaccines demand stringent conditions during storage and distribution. They should only be donated in close collaboration with MoHSW in Tanzania mainland.

An exception may be made for direct donations to specific health facilities, provided that: the Regional Medical Officer (RMO) / District Executive Director (DED) or District Medical Officer (DMO) is notified and the responsible professional at the receiving end acknowledges that (s)he is aware of the shelf life; and that the quantity and remaining shelf-life allow for proper administration prior to expiration. In all cases it is important that the date of arrival and the expiry dates of the medicines be communicated to the recipients well in advance.

3.0 PRESENTATION, PACKING AND LABELING

- a) All medicines must be labelled in the English language; the label on each individual 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. All medicines should be accompanied by prescriber information in the English Language.

Justifications and Explanations

All donated medicines, including those under brand name, should also be labelled with their international non-proprietary name or the official generic name. Training programmes in Tanzania mainland are based on the use of generic names. Receiving medicines under different and often unknown brand names and without the generic name can confuse health workers and constitutes a risk in therapeutic practice.

- b) As far as is possible, donated medicines should be presented in large quantity units and hospital packs as used in Tanzania mainland. Donations of paediatric cough syrups and or mixtures are discouraged. Wherever possible, paediatric medicines should preferably be in solid form, e.g. dispersible tablets, and not liquid formulations.

Justifications and Explanations

Large quantity packs (for example, tins of 1000 tablets) are cheaper and could be easier to transport. This provision also prevents the donations of medicines in sample packages, which are not practical to manage. Donation of paediatric cough syrups and mixtures are discouraged because of little therapeutic value. In general, paediatric formulations in solid dose form are less costly to handle in terms of storage and transport costs and logistics management.

- c) All medicine donations should be packed in accordance with international shipping regulations and be accompanied by a detailed packing list which specifies the contents of each numbered carton by generic name, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 25 kilograms. Different medicines should not be packed together in one carton and medicines should not be mixed with other supplies.

Justifications and Explanations

This provision is intended to facilitate the administration, storage and distribution of donations in emergency situations, as the identification and management of unmarked boxes with mixed medicines is very time consuming and labour intensive. This provision specifically discourages donations of small quantities of mixed medicines. The maximum weight of 25kg ensures that each carton can be opened and handled without special equipment.

4.0 INFORMATION AND MANAGEMENT

- a) Tanzania mainland through the Permanent Secretary for Ministry of Health and Social Welfare should be informed of all medicine donations that are considered, prepared or actually underway. In addition, for regional hospitals, district, health centres and dispensary level donations, the Regional medical officer should be notified in advance by the donor whether the donor is local or international and an agreement should have been made before the medicines are donated. The information should extend to the delivery dates, possible delays, port of entry and method of transport, etc.

Justifications and Explanations

Many medicines donations arrive unannounced. Detailed advance information on all medicine donations is essential to enable Tanzania mainland to plan for the receipt of the donation and to coordinate the donation with other sources of supply. The information should at least include the type and quantities of donated medicines including their generic name, strength, dosage form, and the identity and contact address of the donor.

- b) The declared value to Tanzania mainland of medicine and medical supplies donation should be based upon the wholesale world-market price for its generic equivalent.

Justifications and Explanations

This provision is needed in Tanzania mainland to prevent medicines donations being priced according to the retail price of the product in donor country, which may lead to elevated overhead cost for import tax, clearance, and handling in Tanzania mainland, and consequently undermine the public sector medicine budget in Tanzania mainland.

- c) All costs of international and local transport, warehousing, port clearance, quality testing and appropriate storage and handling should be paid by the donor, unless specifically agreed otherwise with the United Republic of Tanzania in advance. Similarly, the cost of disposing of a medicine donation adjudged to be unsuitable should be borne by the donor. Donors are requested to fill the donation form (Annex 1) annexed with these guidelines prior shipment of goods and submit it to the office of Chief Pharmacist in the Ministry of Health and Social Welfare.

Justifications and explanations

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

Questions and enquiries can be directed to:

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5.0 ANNEX: DONATION CHECKLIST



UNITED REPUBLIC OF TANZANIA
 MINISTRY OF HEALTH AND SOCIAL WELFARE
 Checklist for Donation of Medicines & Medical Supplies

- A) Donor Organisation and address:
- B) Products for Donations: (fill and / or tick related item below and attach proforma invoice where the list is long)

No	Type of product	No. of Unit	Total Value (TZS)	Estimated Supply Chain Costs	Registered / or Cleared with TFDA?
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

C) **Checklist** *(Tick appropriate)*

		MOHSW	MSD	Donor
1	Customs clearing charges	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Demurrage charges	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Import duties	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Storage charges	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Transport to MSD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Transport to Health facilities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Inco terms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

D) Name and contact address of the recipient

E) Name, Address and Signature of Applicant

(Please submit completed form(s) to the office of Chief Pharmacist, MoHSW)

