



PHARMACY AND MEDICINES REGULATORY AUTHORITY
Quality Medicines for Malawi

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GUIDELINES FOR MEDICINE DONATIONS

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1. Abbreviations

- 1.1.** PMRA..... Pharmacy and Medicines Regulatory Authority
- 1.2.** TB.....Tuberculosis
- 1.3.** COA.....Certificate of Analysis
- 1.4.** DG.....Director General

2. Introduction

2.1. Background

This guideline revises the PMRA donation guidelines first published in 2008. The updated version reflects current practices and is designed to address the concerns and challenges faced by all parties involved in processing medicine donation applications.

2.2. Purpose

These guidelines aim to guide in appropriate, ethical, and effective donation of medicines in Malawi, ensuring alignment with public health needs, and safety standards in the donation of medicines while promoting accountability and equity in our resource-limited settings. These guidelines are there to improve the quality of drug donations and not hinder them.

2.3. Scope

The guidelines apply to medicines donated by both local and international donors including manufacturers, distributors, NGOs, and international health agencies, private healthcare institutions, non-profit organizations, and private pharmacies operating legally within Malawi, to the Malawian public or private healthcare providers.

3. Requirements for donation of medicines

- i. All medicine donation must be based on the needs of the recipient. There should be effective communication between the donor and the recipient - donations should be based on an expressed need and should not be sent unannounced.
- ii. Medicine donations must be relevant with respect to the disease pattern in Malawi. They must also be relevant with respect to the level of care (health center, district or central hospital etc.). i.e. For example, a medicine meant for use at the central hospital level should not be made available at the lower level facility such as district hospital or a health center.
- iii. Medicines donated must be those that appear on the Malawi Standard Treatment Guidelines (MSTG), Malawi Essential Medicines List (MEML) and in alignment to existing government drug policies and treatment guidelines.

- An exception can be made in cases of orphan drugs and medicines needed in outbreaks or newly emerging diseases.
- iv. All donated medicines must be in quantities that will be consumed by the recipient within their shelf life.
 - v. The dosage form, strength and formulation of donated medicines, should be similar to those commonly used in Malawi.
 - vi. All donated medicines must have originated from licensed suppliers and comply with quality standards in both the donor country and in Malawi. If the quality, safety and efficacy of a medication is unacceptable in the country from which it originates, it is also unacceptable as a donation in Malawi.
 - vii. No medicines should be donated that have been issued to patients and then returned to pharmacies or clinics. This also applies to those given to health professionals as free samples.
 - viii. Labelling of the medicines must be in English and not any other language that can not be understood by Malawians. The generic name of the medication must always be included to make identification possible. The label must also include the batch number, dosage form, strength of the medicines, name of the manufacturer, quantity in the container, storage conditions, date of manufacture as well as date of expiry.
 - ix. Donated medicines must have at least 12 months of shelf life on receipt. An exception can be made provided there is assurance from the recipient that the quantities to be donated will be consumed before the expiry date depending on their consumption of the particular medicine.
 - x. Narcotics and psychotropics (controlled substances) require an additional permit (Narcotic license) for import obtained from PMRA.

4. Application for donation of medicine

4.1.Key relevant documents

The following documents are required and relevant when making a medicine donation application:

- i. A cover letter summarizing the donation application addressed to the Director General of PMRA.

- ii. A completed Drug Donation Form PMRA/D/001 giving all the details as requested. This form can be downloaded on the PMRA website www.pmra.mw or found in Annex 2. Annex 1 Provides guidelines on how to fill and complete the donation Form.
- iii. An invoice/s of the consignment of the medicines to be donated from a licensed supplier.
- iv. Proof of Payment of the applicable fees.
- v. Certificate of donation from the donor.
- vi. Certificates of Analysis (COA) of the different medicine batches, where applicable.
- vii. A completed Form 8CD for narcotic and psychotropic medicine donation. This form can be downloaded from the PMRA website. Alternatively, a corresponding narcotic license issued by PMRA, if available.
- viii. In the event that the donation is for the Ministry responsible for health, a letter from the District Health Office.

4.2.Submission of the application

There are two ways for submission of the medicine donation application to PMRA:

- i. In-person submission of the necessary documents at the PMRA offices in Lilongwe at the following address:
 - Director General
 - Pharmacy and Medicines Regulatory Authority
 - Off Paul Kagame Road,
 - P.O. Box 30241,
 - Lilongwe 3, Malawi.
- ii. Alternatively, send scanned copies of the documents via email to info@pmra.mw and copy dg@pmra.mw

4.3.Processing and review of medicine donation application

PMRA will process and review the donation application within 10 working days, and the applicant shall be given feedback accordingly. The review will be based on the requirements for medicine donation as stated in sections 3 and 4.1 of this document.

Upon review of the application, the following are the possible outcomes that are communicated to the applicant accordingly:

- i. Approval of the donation
- ii. Deferred/pending for additional documentation
- iii. Rejected

In case there is a need for additional information/documentation, the applicant shall be contacted accordingly to provide the additional documents. Upon satisfaction of this, the review shall proceed.

5. References

- i. Guideline for donation of medicines, medical devices, and IVDs SAHPRA, 2025
- ii. Guidelines for medicines donations to the Republic of Zimbabwe, MCAZ, 2024
- iii. WHO Guidelines for Medicine Donations (4th edition)

Annex 1: Guidelines for drug donations for Malawi

Instructions on how to complete the request form for the importation of a medicine as a donation

1. Read the instructions carefully before completing the Form No. PMRA/D/001 attached, which is the only form to be completed. Upon completion, the form, together with other necessary documents, must be submitted to the PMRA offices or can also be scanned and emailed to dg@pmra.mw.
2. On the Form;
 - a. The **Applicant** is the party in Malawi in contact with the Donor arranging the donation.
 - b. The **Beneficiary** is the recipient of the donation e.g., hospital or clinic, and it may not necessarily be the applicant. The Beneficiary has to express willingness to accept the items included in the donation, and a letter to that effect has to be attached.
 - c. The **Responsible Person** is the individual who would be able to provide clarification, where necessary, to any part of the completed application
3. The form must be completed in liaison with the potential donor, who should provide particulars about the medicines earmarked for donation in terms of the following:
 - a. Date of Manufacture of the medicine (from the label placed by the manufacturer)
 - b. Date of Expiry of the medicine (from the label placed by the manufacturer)
 - c. Name and address of the manufacturer and the country of origin
 - d. Name and address of Supplier if different from the Donor or Manufacturer.
 - e. Delivery time may be quoted in months or weeks. This is also meant to alert the recipient to prepare for consignment. It should also give an indication as to whether the product will arrive with the required shelf life or if it can be utilized before expiry given the

quantity indicated

4. Correspondence between donor and applicant/recipient may be attached to the application where necessary
5. Each item will be evaluated in its own right, hence each entry will either be approved or rejected. If an item is rejected, the reason(s) will be given and will always be in line with the provisions in the guidelines.
6. Each item will be assigned an official PMRA number. This is not a Registration number; hence, if the same item is included in a future donation, a new number will be assigned.
7. An official stamp of the Applicant/Recipient should be put on each document submitted.
8. The Applicant/Recipient shall complete a single copy only; the PMRA will make a further copy of the completed form showing the approved/rejected items and distribute the copies as indicated in the guidelines
9. Costs of international and local transport, warehousing, port clearance, and other related costs should be paid by the donor agency, unless agreed otherwise with the recipient in advance.
10. Value of donation may be declared based on prevailing generic equivalent costs in Malawi at the time of delivery
11. Any requests for further clarification on how to complete the form should be made to the Director General of PMRA at the address and contact details given.

Annex 2: Drug Donation Form (PMRA/D/001)

REQUEST FOR IMPORTATION OF A MEDICINAL PRODUCT AS A DONATION

1. NAME AND ADDRESS OF APPLICANT: _____

Phone: _____ E-mail: _____

Name of Responsible Officer: _____

2. NAME AND ADDRESS OF BENEFICIARY (If different from 1): _____

Phone: _____ E-mail: _____

Contact Person: _____

3. NAME AND ADDRESS OF THE DONOR: _____

Phone: _____ E-mail: _____

Contact Person: _____

4. LIST OF MEDICINES PROPOSED FOR DONATION

Item Description (Includes generic and brand name, strength, pack size. and quantity requested)	Man. Date (mm/yy)	Expiry Date (mm/yy)	Manufacturer	Country of origin	Supplier (if applicable)	Delivery time (wk.)	Approved or Rejected and Remarks	PMRA Ref. No.

Items No. Approved.....Director General PMRA

Date/Stamp

Items No. Rejected..... Director General PMRA

Date/stamp.....

Name of Customs Clearing Office.....

Authorized Name and Signature.....

Date/stamp.....

Port of entry: