Medicines Control Authority of Zimbabwe

MCAZ/LED/GL-13

GUIDELINES FOR MEDICINES DONATIONS TO THE REPUBLIC OF ZIMBABWE

EFFECTIVE DATE: 02/2022

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ACRONYMS

CEO	Chief Executive Officer
cGMP	Current Good Manufacturing Practice
DPS	Directorate of Pharmacy Services
EDLIZ	The Essential Medicines List of Zimbabwe
INN	International Non-proprietary Name
MCAZ	Medicines Control Authority of Zimbabwe
MASCA	Medicines and Allied Substance Control Act
MOHCC	Ministry of Health and Child Care
NatPharm	National Pharmaceutical Company of Zimbabwe
WHO	World Health Organisation
ZNMP	Zimbabwe National Medicines Policy
EMP	Essential Medicines Programme

1.0 APPLICATION

The guidelines are directed to potential medicine donors including all persons and organisations that may solicit medicine donations and were developed primarily to ensure that all donations meet the express needs of recipients in Zimbabwe.

2.0 PURPOSE

These guidelines are meant to ensure that donations are fully utilised and have been prepared in line with those published by World Health Organisation (WHO), together with some modifications to suit the specific needs of Zimbabwe.

3.0 BACKGROUND / INTRODUCTION

Donations, if appropriate, can provide valued assistance in supporting the existing health care services of a government that has an ever-increasing burden of financing the health needs of the country with limited resources. Zimbabwe has benefited in the past from various medicine donations and it is hoped that this will continue. On many occasions, Zimbabwe had to meet considerable unexpected expenditure to process donations that had not been properly planned.

This guideline details the following aspects;

3.1 How medicines are selected,

3.2 Quality assurance

3.3 Expected shelf life of the medicines,

3.4 Presentation, packaging and labelling of the medicines,

3.5 Management of the donations.

4.0 DEFINITIONS

5.0 GUIDELINES

5.1 Selection of medicines

All medicine donations must be based on an expressed need and be relevant to the disease pattern in the Republic of Zimbabwe. Except in acute emergencies, medicines should not be sent without prior clearance by Zimbabwe. Donations to specific primary health facilities may only be received at that level on the express written authority from the higher levels, the Provincial Medical Director/District Medical Officer as the case may be. In all

cases it is important that the donation be cleared and approved well in advance before being communicated to the recipients.

5.1.1 Justifications and Exceptions

This 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.

5.1.2 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 (2013).
https://www.who.int/medicines/publications/essentialmedicines/18th_EML.pdf

5.2 All donated medicines must appear in the latest version of the Essential Medicines List for Zimbabwe (EDLIZ).

5.2.1 Justifications and Explanations

This provision is intended to ensure that medicine donations comply with the Zimbabwe National Medicines Policy (ZNMP) and the Essential Medicines Programme (EMP). These guidelines aim at maximizing the positive impact of the donation, and prevents the donation of medicines which are unnecessary and/or unknown in the Republic of Zimbabwe.

5.2.2 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 the Republic of Zimbabwe. Exceptions can also be made on the basis of a specific request to the Government of Zimbabwe.

5.3 The dosage form, strength and formulation of donated medicines, should be similar to those commonly used in the Republic of Zimbabwe.

5.3.1 Justifications and Explanations

The staff working at different health care levels in the Republic of Zimbabwe have 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 medication errors.

5.4 All donated medicines have to originate from a reliable source and comply with quality standards in both the donor country and the Republic of Zimbabwe. The WHO

Certification Scheme on the Quality of Pharmaceutical Products moving in to International Commerce should be used, and relevant batch-certificates to be included. All donated medicines must be registered by the Medicines Control Authority of Zimbabwe (MCAZ). In the exceptional cases where this is not possible, donated medicines must be cleared by the MCAZ before they can be released for distribution. The approval for these donations falls under Section 75 of the Medicines and Allied Substances Control Act (MASCA).

5.4.1 Justifications and Explanations

The provision ensures that countries do not donate medicines that have been deemed not to meet quality standards in their own country. Donated medicines should be authorized for sale in the country of origin, and manufactured in accordance with international standards of current Good Manufacturing Practice (cGMP).For donations for products that are not authorized for sale in the country of origin, please refer to the *Guideline on the requirements for permitting the marketing authorisation of products not produced in Zimbabwe and not authorized in the country of origin* for the documentation required.

5.4.2 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 Zimbabwean producers, the requirement does not apply.

5.5 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.

5.5.1 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 Zimbabwe 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.

5.5.2 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 of the MOHCC and MCAZ.

5.6 After arrival in the Republic of Zimbabwe all donated medicines should have a remaining shelf-life of at least one year.

5.6.1 Justifications and Explanations

Under emergency situations, there may be logistical problems limiting immediate distribution. Distribution through different storage levels (e.g. central store, provincial store, district hospital) 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.

5.6.2 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 the MOHCC in Zimbabwe.

An exception may be made for direct donations to specific health facilities, provided that: the Provincial Medical Director/Chief Executive Officers (CEO) or Medical Superintendent 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.

5.7 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.

All medicines should be accompanied by prescriber information in the English language.

5.7.1 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 Zimbabwe 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.

5.8 As far as is possible, donated medicines should be presented in large quantity units and hospital packs as used in the Republic of Zimbabwe (see NatPharm catalogue). Donations of paediatric syrups and mixtures are discouraged.

5.8.1 Justifications and Explanations

Large quantity packs (for example, tins of 1000 tablets) are cheaper, and easier to transport. This provision also prevents the donations of medicines in sample packages, which are not practical to manage. Donations of paediatric syrups and mixtures are discouraged because of high transport and storage costs.

5.9 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.

5.9.1 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 25 kg ensures that each carton can be opened and handled without special equipment.

5.10 The Republic of Zimbabwe through the Secretary for Health and Child Care and NatPharm should be informed of all medicine donations that are considered, prepared or actually underway. In addition, for provincial hospitals, district, missions and clinic level donations, the Provincial Medical Director 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.

5.10.1 Justifications and Explanations

Many medicine donations arrive unannounced. Detailed advance information on all medicine donations is essential to enable the Republic of Zimbabwe 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. See also 5.1.7 above.

5.11 The declared value to the Republic of Zimbabwe of medicine donation should be based upon the wholesale world –market price for its generic equivalent.

5.11.1 Justifications and Explanations

This provision is needed in the Republic of Zimbabwe to prevent medicine 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 the Republic of Zimbabwe. It may also result in a corresponding decrease in the public sector medicine budget in the Republic of Zimbabwe.

5.12 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 Republic of Zimbabwe in advance. Similarly, the cost of disposing of a medicine donation adjudged to be unsuitable should be borne by the donor.

5.12.1 Justification and explanation

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

5.13 Documentation required for donated products

5.13.1 The donated medical products should meet the requirements listed in *LEF 78 Rev 1_July 2020_Checklist for importation of donation (see* Appendix I) before approval.

5.13.2 For handling applications for donations, please refer to *LE 08 Rev 5 July 2020 SOP for Handling Applications for Donations.*

6.0 KEY RELEVANT DOCUMENTS

6.1 Guidelines on the requirements for permitting the marketing authorisation of products not produced in Zimbabwe and not authorized in the country of origin
6.2 LEF 78 Rev 1_July 2020_Checklist for importation of donation
6.3 LE 08 Rev July 2020 SOP for Handling Applications for Donations
6.4 Medicines and Allied Substance Control Act

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	New document
N/A	N/A	

APPENDIX I: CHECKLIST FOR IMPORTATION OF DONATIONS

LEF 78

LICENSING AND ENFORCEMENT DIVISION

CHECKLIST FOR IMPORTATION OF DONATIONS

REQUIREMENTS	YES	NO
Documentation from the applicant/donor clearly stating the name and address of the recipient, distribution agent as well as donation certificate or supporting letter.		
Detailed list of the medicines to be donated bearing all the information on generic names, manufacturers, expiry dates and the remaining shelf life (at least one year) and quantities should be submitted.		
The certificates of analysis for the batches of donated medicines should be attached.		
Expected date of arrival, mode of transport and port of entry should be stated.		
The medicines to be donated should be registered by the Medicines Control Authority of Zimbabwe (MCAZ). In the exceptional cases where this is not possible, they must be cleared by the MCAZ before they can be released for distribution.		
Each individual container for the medicine should be clearly labelled in English and should bear the international non-proprietary name (INN) or generic name.		

N.B Please be advised that such authorisation is granted prior to the dispatch of the consignment from the country of origin and not upon arrival at the port of entry. Upon arrival in Zimbabwe, the medicinal consignment will be verified by physical examination by Regulatory officers from the MCAZ.