

# GUIDELINES FOR MEDICINES DONATIONS TO THE REPUBLIC OF ZIMBABWE

Reviewed by the  
Directorate of Pharmacy Services

Ministry of Health and Child Welfare

June 2012



**Health**  
Transition Fund

Supporting the National Health Strategy  
to improve access to quality health  
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# Guidelines for Medicines Donations to The Republic of Zimbabwe



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# FOREWORD

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Donations, if appropriate, can provide valued assistance in supporting the existing health care services of a government which has an ever increasing burden of financing the health needs of the country with limited resources.

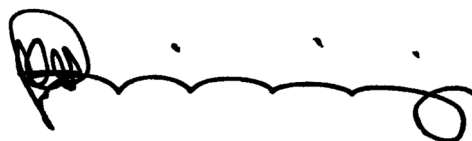
Zimbabwe has benefited in the past from various medicine donations and it is hoped that this will continue. On many occasions Zimbabwe has had to meet considerable unexpected expenditure to process donations that had not been properly planned. To ensure that donations are fully utilized, the guidelines have been prepared in line with those published by WHO, with some modifications to suit the specific needs of Zimbabwe.

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 Zimbabwe.

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 in the past had to make, choosing either to 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.



Brigadier General (Dr) Gerald Gwinji  
SECRETARY FOR HEALTH AND CHILD WELFARE

# ABBREVIATIONS

CEO	Chief Executive Office
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
MOHCW	Ministry of Health and Child Welfare
NatPharm	National Pharmaceutical Company of Zimbabwe
PMD	Provincial Medical Directorate
UN	United Nations
WHO	World Health Organization
ZNMP	Zimbabwe National Medicines Policy

ABBREVIATIONS



## SELECTION OF MEDICINES

- 1** 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.

### **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.

**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.

# Selection of Medicines

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

## **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. 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.

**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.

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

## **Justifications and Explanations**

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

# B

## QUALITY ASSURANCE AND SHELF LIFE

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- 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 International Commerce should be used, and relevant batch-certificates 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.

### **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 authorized for sale in the country of origin, and manufactured in accordance with international standards of current Good Manufacturing Practice (cGMP).

**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** 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



## Quality assurance and shelf life

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.

**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 MOHCW and MCAZ.

### **6** After arrival in the Republic of Zimbabwe 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 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.

**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 MOHCW 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.

# C

## PRESENTATION, PACKING AND LABELING

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**7** All medicines must be labeled 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:

1. batch number,
2. dosage form,
3. strength of the medicines,
4. name of manufacturer,
5. quantity in the container/bottle or box,
6. storage conditions,
7. date of manufacture and
8. Expiry date, as clear dates not codes.

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 labeled 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.

## Presentation, Packing and Labeling

- 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.

### **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.

- 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.

### **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.

# D

## INFORMATION AND MANAGEMENT

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**10** The Republic of Zimbabwe through the Secretary for Health and Child Welfare 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.

### **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 7 above.

# Information and Management

**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.

## **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.

**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.

## **Justification and explanation**

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

# QUESTIONS AND ENQUIRIES

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### **Questions and enquiries can be directed to:**

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