Kingdom of Swaziland
Ministry of Health

SWAZILAND GUIDELINE ON DONATION OF MEDICINES

January 2016

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FOREWORD

These Guidelines aim to improve the quality of medicine donations received by the Government of the Kingdom of Swaziland.

There are various scenarios for medicine donations:

- they may take place in acute emergencies or as part of development aid in non-emergency situations;
- they may be corporate donations from pharmaceutical companies (direct or through private voluntary organizations), including donations for compassionate use;
- they may be in the form of aid by governments; or
- they may be donations aimed directly at single health facilities.

Although there are legitimate differences between these scenarios, there are many basic rules for an appropriate donation that apply to all. The Guidelines aim to describe this common core of "Good Donation Practice".

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Director: Health Services

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Ms. Fortunate Bhembe
Chief Pharmacist: MOH

1.0 INTRODUCTION

1.1 Aim

The guidelines aim to describe the common core of good medicine donation practice.

1.2 Guiding Principles

The *Swaziland Guidelines on Medicine Donations* is based on four core principles that form the basis of good medicine donation practice as recommended by the World Health Organisation, namely:

1. Donations of medicines should benefit the recipient to the maximum extent possible. All donations should be based on an expressed need. Unsolicited medicine donations are to be discouraged.

2. Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with the government policies and administrative arrangements of the recipient country.

3. There should be effective coordination and collaboration between the donor and the recipient, with all donations made according to a plan formulated by both parties.

4. There should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation

1.3 Definition of Medicines

Medicines, as defined by the Medicines and Related Substances Control Act, are defined as follows:

(a) Medicine means any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in–

(i) the diagnosis, treatment, mitigation, modification, prevention of diseases or any abnormal physical or mental state or symptoms of any abnormal or mental state in humans or animals; or

(ii) restoring, correcting or modifying a physical, mental or organic function in humans or animals; and

(b) includes a complementary medicine; or

(c) means a substance or mixture of substances declared by the Minister, in consultation with the Authority, by notice in the Gazette to be a medicine or a complementary medicine, and excludes a veterinary drug and medicinal substance.

1.4 Scope of the Guidelines

The guidelines cover the following types of donation:

- Donations in emergencies situations;
- Donations from other governments as part of development aid;
- Corporate donations from pharmaceutical companies (direct or through private voluntary organizations), including donations for compassionate use;
- All medicine procurements that are funded by Agencies other than the GKoS;
- Donations aimed directly at single health facilities; or
- Medicines to be used by health care workers during the provision of outreach clinical services in Swaziland that are imported by the health care workers or their Agencies.

2.0 GUIDELINES FOR MEDICINE DONATIONS

I. **Before a donation is sent to Swaziland, the Office responsible for Medicine Regulatory activities and the Central Medical Stores should be contacted by the potential donor (or vice versa) in order to establish the need for such medicines at that time. <u>All</u> donations must go through the Central Medical Stores; <u>no</u> donations should go directly to a health facility.**

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.

In acute emergencies, the need for prior consent by the Office responsible for Medicines Regulatory activities and the Central Medical Stores may be waived, provided that the medicines are among those on the Swaziland Essential Medicines List or are included in the United Nations list of emergency relief items recommended for use in acute emergencies.

II. **Donations must consist only of medicines of known good quality that are included in the most recent version of the National Essential Medicines List and Standard Treatment Guidelines of Swaziland.**

It is expected that donors will comply with the most recent Swaziland National Pharmaceutical Policy and essential medicines programme and thus contribute to the implementation of their components, such as the provision of medicines which are considered to be necessary in the treatment of diseases afflicting most people in Swaziland.

An exception can be made for medicines needed in sudden outbreaks of uncommon or newly emerging diseases. However, if these medicines are not approved for use in Swaziland, donors should duly inform the Office responsible for Medicines

Regulatory activities and the Office of the Chief Pharmacist of the regulatory status of products to be donated, and should obtain consent before importation.

III. **All donated medicines must be registered in the countries of origin, and manufactured in conformity with the guidelines on current Good Manufacturing Practices (cGMP) or certified according to the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce or the WHO Prequalification of Medicines Programme.**

This provision prevents double standards: medicines of unacceptable quality in the donor country should **not** be donated to Swaziland. 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). This also guards against spurious, substandard, falsified, falsely-labelled and counterfeit products.

IV. **Medicines that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples should NOT be donated to Swaziland.**

Patients return unused medicines to a pharmacy to ensure their safe disposal, among other reasons; the same applies to medicine samples that have been received by health workers. Returned medicines should not be donated because their quality cannot be guaranteed.

V. **All medicines should be labelled in at least one of Swaziland's official languages; the label on each individual container should at least contain the International Non-proprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.**

All donated medicines, including those under brand name, should also be labelled with their INN or the official generic name. The INN's are internationally known and understood in any country where Roman script is used. Receiving medicines under different and often unknown brand names and without the INN is confusing for health workers and can even be dangerous for patients. In the case of injections, the route of administration should be indicated.

VI. After arrival in Swaziland, all donated medicines should have a remaining shelf-life of <u>at least one year</u>. In all cases it is important that the date of arrival and the expiry dates of the medicines be communicated to the Central Medical Stores well in advance.

It is important that the Central Medical Stores official responsible for acceptance of the donation is fully aware of the quantities of medicines being donated, as well as their expiry dates, so as to avoid overstocking that may lead to wastage.

VII. The presentation, strength and formulation of donated medicines should, as far as possible, be similar to those of medicines commonly used in Swaziland.

The reason for this is that health workers at different levels of the health care system have been trained to use medicines in relation to a particular dosage and strength, and local treatment schedules have been developed accordingly. Furthermore, health workers with insufficient training in making necessary calculations to modify schedules may end up giving wrong dosages.

VIII. As far as possible, donated medicines should be presented in larger quantity units and hospital packs (rather than individual patient-ready packs).

Larger quantity packs and hospital packs are less bulky, and therefore easier and cheaper to handle. They also allow for more effective distribution and dispensing

to patients. When possible, liquid formulations (syrups and mixtures) should be avoided because of their more demanding logistical needs.

IX. The costs of international and local transport, warehousing, port clearance and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with Swaziland <u>in advance</u>.

This provision prevents the Government of the Kingdom of Swaziland from being forced to spend effort and money on the clearance and transport of unannounced consignments of unwanted items, and also enables the Swaziland Government to review the list of donated items at an early stage.

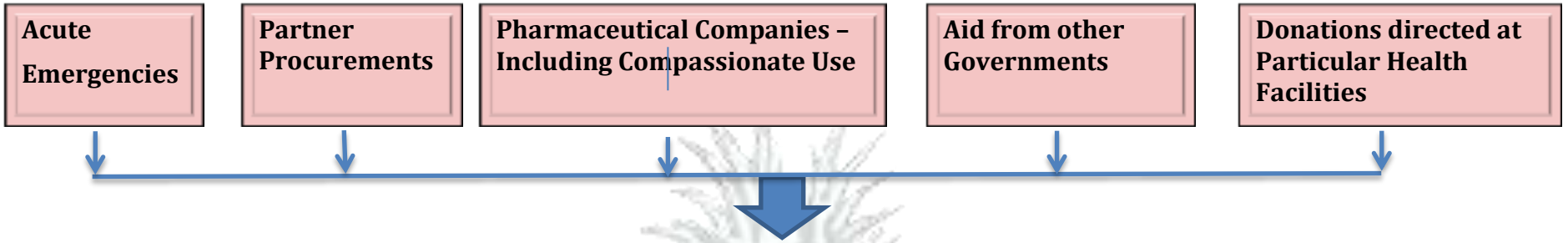
ANNEX 1. SWAZILAND DONATION GUIDELINE ON MEDICINE FLOW / QUICK REFERENCE

I. Medicine to be donated should be the ones in the Swaziland Essential Medicines List

II. Medicines to be donated must be registered and used in their country of normal origin, they must be labelled in English and they should have remaining shelf life of not less than ¾ of their shelf life

III. All pharmaceutical donations coming to the Ministry of Health must be sent to Central Medical Stores

IV. The diagram below demonstrates the flow of all donations (and procurements of medicines for the public sector that are being carried by any party other than the Ministry of Health).



Before a Donation is sent to the Ministry of Health:

A. A written intention of the proposed donation, the description of the products to be donated and their quantities should be send to the office responsible for medicine regulation

B. The office responsible for Medicines Regulation should give a written Authority to the Donor accepting the proposed donation

C. The Donor should inform the office responsible for Medicine Regulation of the proposed delivery date of the donation and forward all Donation paper work (Invoices, Picking List, Airway Bill/Bill of landing)

D. The Ministry should seek VAT exemption Authority from SRA for the Donation and forward the exemption authority to the donor

E. Pharmaceuticals delivered to and distributed by Central Medical Stores