MINISTRY OF HEALTH

Quality Medicines for Malawi

PHARMACY AND MEDICINES REGULATORY AUTHORITY

Guidelines for Drug Donations for Malawi

February 2008

Guidelines for Drug Donation in Malawi

1. Introduction

These guidelines aim to improve the quality of drug donations and not hinder them. The guidelines cover all scenarios for drug donations though special arrangements may be necessary in acute emergency situations. The guidelines are to be used by both the public and private sector institutions in Malawi.

2. The Need for having Guidelines

The guidelines are designed to improve the quality of donations specifically in the following areas:

(a) Relevance of donation to the local situation with respect to disease pattern, level of care (health centre, district or central hospital etc), drug policies and treatment guidelines (particularly for major diseases like malaria and TB). Some medicines are dangerous and may have been banned in many countries. All donors are expected to observe local policies with regard to distribution of medicines. For example a medicine meant for use at the central hospital level should not be made available at the lower level facility such a s a district hospital or a health centre

(b) Labeling of medicines in a language that can be understood in Malawi. Always the generic name must be included to make identification possible. Preference to be given to medicines on register of the Pharmacy and Medicines Regulatory Authority

(c) The quality of the medicine is a major factor for consideration. Donated medicines will have at least 1 year shelf life (where applicable) on receipt in Malawi. Drugs and free samples returned to pharmacies/clinics (usually not in original containers) are not acceptable. Medicines that are not acceptable in the donor country on account of quality would not be considered..

(d) Medicines will be donated in presentations, strength and formulations commonly used or accepted in Malawi. Quantities may be vetted as necessary to ensure that there is no overstocking which may create problems of disposal.

(e) Donations must always be based on sound analysis of needs; hence there should always be communication between the donor and recipient in the initial stages of planning for a donation. Prior consent by the recipient in Malawi is necessary before the donation is initiated.

3. Steps to be followed in the implementation of policy on drug donations

a) The recipient defines needs and makes contact with a potential donor (Pharmacy department of the institution in Malawi to coordinate)

b) PMRA Request Form No. PMRA/D/01 is completed by applicant giving all details as requested. Additional information where applicable may be sent on a headed paper. One copy is needed but the PMRA will make additional copies for distribution to relevant authorities after the approval process is completed.

c) The completed copies of Form No: PMRA/D/01 are distributed as follows:

The applicant collects Three (3) copies to be distributed as follows:

i) **Original** kept by Applicant

ii) **Copy 1** to Donor

iii) **Copy 2** to the department of customs and excise (Port of entry) to facilitate clearing on arrival of consignment

iv) **Copy 3** to CMS to reconcile national requirements sent by the PMRA

v) **Copy 4** remains with the PMRA

d) Criteria for rejecting or approving an item as a donation is based on the core principles covered under 2 but summarized as follows:

i) Maximum benefit to the people of Malawi (Medicine must be register-able in Malawi or should appear on the Malawi Essential Drug List).

ii) Donation meets the wishes of the recipient in Malawi.

iii) Donation complies with Malawi National policies on drugs and fit in the treatment guidelines.

iv) Quality of supplies is assured e.g. shelf life, labeling etc. Products failing to meet the minimum quality requirement could be rejected

e) A committee of officials from the MOH and PMRA will do the approval of a medicine as a donation within ten (10) days of receipt of an application. Decisions by the committee will be final and the registrar of PMRA will endorse the approval by signing at the appropriate section of the application form. (Processed Application forms may be sent by FAX to the applicant / recipient if feasible).

f) Where a donation arrives without following the guidelines for donations, the medicine(s) will be impounded at the border entry point. If the intended recipient expresses interest in the consignment, arrangements will be made at the recipient's expense to have the consignment inspected and assessed for quality. If the consignment fails quality assurance tests it will be disposed off professionally at the recipient's expense.

4. Abbreviations used in these guidelines and in the Annex

PMRA …….Pharmacy, Medicines & Poisons Board
MOH ……. Ministry of Health
CMS ……..Central Medical Stores

NB. Drugs and Medicines are used interchangeably in these guidelines

ANNEX TO GUIDELINES FOR DRUG DONATIONS FOR MALAWI

SECTION 1

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/100 attached which is the

only form to be completed and returned to: ***The Registrar, Pharmacy, Medicines & Poisons Board, P.O. Box 30241, Lilongwe 3. Phone: 265 1 755 166 / 165 Fax: 265 1 755 204 E-mail: admin@PMRA.malawi.net***

2. The **Applicant** is the party in Malawi in contact with the Donor arranging the donation.

3. 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.

4. The **Responsible Person** is the individual who would be able to provide clarification where necessary to any part of the completed application form.

5. 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 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

6. Correspondence between donor and applicant/recipient may be attached to the application where necessary

7. Each item will be evaluated 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.

8. 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.

9. An official stamp of the Applicant / Recipient should be put on each document submitted.

10. The Applicant /Recipient shall complete a single copy only, however the PMRA will make a further copies of the completed form showing the approved / rejected items and distribute the copies as indicated in the guidelines

11. 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.

12. Value of donation may be declared based on prevailing generic equivalent costs in Malawi at the time of delivery

13. Any requests for further clarification on how to complete the form should be made to the Registrar at the address and contact details given in 1