

Practical Pharmacy For Developing Countries

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Note to our readers:

The goal of Practical Pharmacy is to provide accessible, objective and accurate information on medicines issues for front-line health workers who may not have any pharmaceutical training. In this issue we focus on medicines donations and highlight good medicines donation practices. Medicines donations sent to “help” developing countries can actually do more harm than good if proper guidelines are not followed. Medicines donations are necessary and valued when they accurately meet the recipient’s needs. However, guidelines should be followed and international regulations developed to ensure that donations are effective, safe and useful to those most in need. In this issue of Practical Pharmacy we focus on the following:

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We welcome your feedback to know if we have been successful in achieving our goal with this issue. Contact us at practicalpharmacy@gmail.com

Medicine Donations



Credit: EPN

Sources of medicine donations include private individuals / companies, Non-Governmental Organisations, UN agencies and foreign governments. Recipients of these donations are usually countries in need, which may be due to a lack of resources or a sudden increase in need for medicines due to a natural disaster or other emergency. Donors, in theory, have good intentions but in reality, donations are often inappropriate and may even become a burden to recipient countries. It is crucial that donation guidelines be followed, for the process to be organized and effective.

Some countries have reported up to 60% of the medicines donated being “inappropriate.” Inappropriate medicines fall into two categories; Unusable and Useless Medicines.

1. Unusable medicines; are those which have been damaged, expired, spoiled (from storage or transportation), or are unidentifiable.
2. Useless medicines; are those for which there is no clinical need for the population in the recipient country. The recipient country bears the burden of storing and disposing of inappropriate medicines.

A store with a shipment of medical supplies.

Core principles for a donation

There must be systems in place to sort inappropriate medicines from appropriate ones. This article will discuss systems which are employed at the sending and receiving phase. The goal of these systems is to improve medicines donations so that more beneficial and "appropriate" medicines will be donated in the future.

Maximum benefit to the recipient

The first and paramount principle is that a medicines donation should benefit the recipient to the maximum extent possible. This implies that all donations should be based on an expressed need and that unsolicited donations are discouraged. The guiding rules are:

1. A donation should be made with full respect for the wishes and authority of the recipient, and be supportive of existing government health policies and administrative arrangements.
2. There should be no double standards in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.
3. 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.



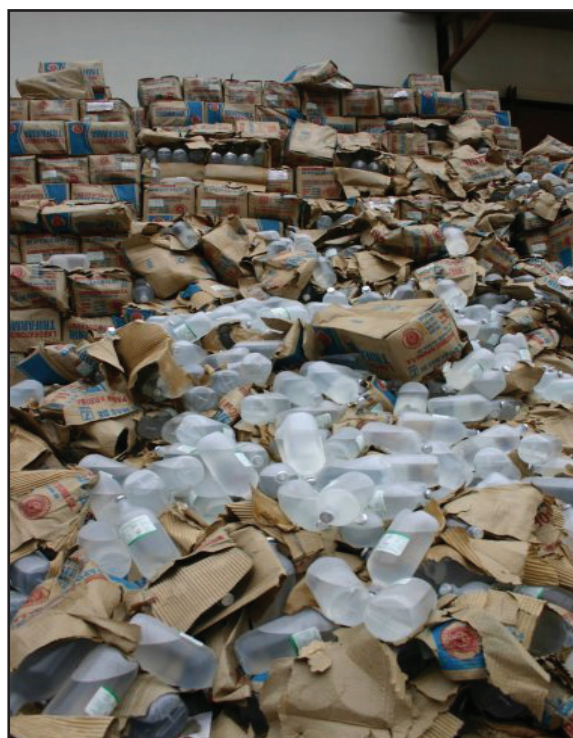
Credit: EPN

A worker inspects donated medicines

In 1990, a large consignment of medicines was sent to a war-devastated Southern Sudan. Each box contained a collection of small packets of medicines. Some were open / partly used. All were labelled in French, a language not spoken in Sudan. Most medicines were inappropriate; some were considered dangerous. These included: contact lens solution, appetite stimulants, anti-depressants, X-ray solutions, medicines for high cholesterol, and expired antibiotics. Of 50 boxes, only 12 contained useful medicines.

It appears that some donor countries view donations as a form of "medicines disposal." The cost of destroying just one ton of medicines may be as high as USD\$ 2000. Donors may thus save the cost of disposing medicines by transferring the cost to the recipient country. Donors may also enjoy benefits, such as stature or tax deductions, from their "humanitarian" gifts.

In 1993 eight tons of donated medicines were sent to Guinea-Bissau. The donation contained 22,123 packages of 1,714 different medicines which were very difficult to manage and greatly interfered with government efforts to rationalize medicines supply and use.



Inappropriate donations leading to medicines

wastage in Banda Aceh www.drugdonations.org

Medicine Donation Checklist for Donors

Principle	Yes / No
<p style="text-align: center;">SELECTION</p> <p>Medicines are on the Essential Medicines List (EML) of the recipient</p> <p>Recipient has accepted to these medicines</p> <p>Medicines are registered for use in the country or on the WHO model EML</p> <p>Presentation, strength and formulation similar to what is available in recipient country</p>	
<p style="text-align: center;">QUALITY ASSURANCE AND SHELF-LIFE:</p> <p>Medicines are from a reputable supplier</p> <p>Supplier is accredited with the donor and recipient countries</p> <p>Donated medicines are not returns from patients or samples from healthcare providers</p> <p>Medicines have a shelf-life of at least one year when they arrive in the recipient country (and staff are made aware of any medicines with shorter shelf-lives)</p>	
<p style="text-align: center;">PRESENTATION, PACKAGING AND LABELING:</p> <p>Medicines are labeled in a language that will be understood by health professionals in the recipient country</p> <p>Medicines are labeled according to their International Non-proprietary names (INN)</p> <p>Medicines are supplied in bulk</p> <p>Medicines are packed according to international shipping regulations</p> <p>Labels contain the following information: batch number, dosage form, strength, name of manufacturer, quantity, storage conditions, expiry date</p>	
<p style="text-align: center;">INFORMATION AND MANAGEMENT</p> <p>Recipients are informed of the proposed donation(s)</p> <p>Value of the donations is based on wholesale prices in the recipient country, or wholesale world-market prices</p> <p>Agreement is made on payment of shipping, transport, warehousing, storage and handling</p> <p>Feedback is received from recipient country and is used to improve future donations</p>	

Receiving Medicines Donation



Credit: EPN

MEDS staff loading vehicle at dispatch

Receiving of Medicines Donations

Medicines that are donated are often accepted in their current state, especially during emergencies. However, without proper guidelines in place for receiving donated medicines, the recipient country will run the risk of having a large amount of **unwanted** medicines. The cost of removing unwanted medicines can be as costly as buying medicines, as it would require many workers checking, organizing and transporting the

medicines. This would be even more **detrimental** in a country that already requires assistance.

Although sometimes it is not within the recipient's control to stop medicines arriving unannounced during emergency aid, even a little **communication** between donor and recipient will make an improvement in the appropriateness of the donation. An important message is that it is as much responsibility of the recipient as that of the donor to manage donations.

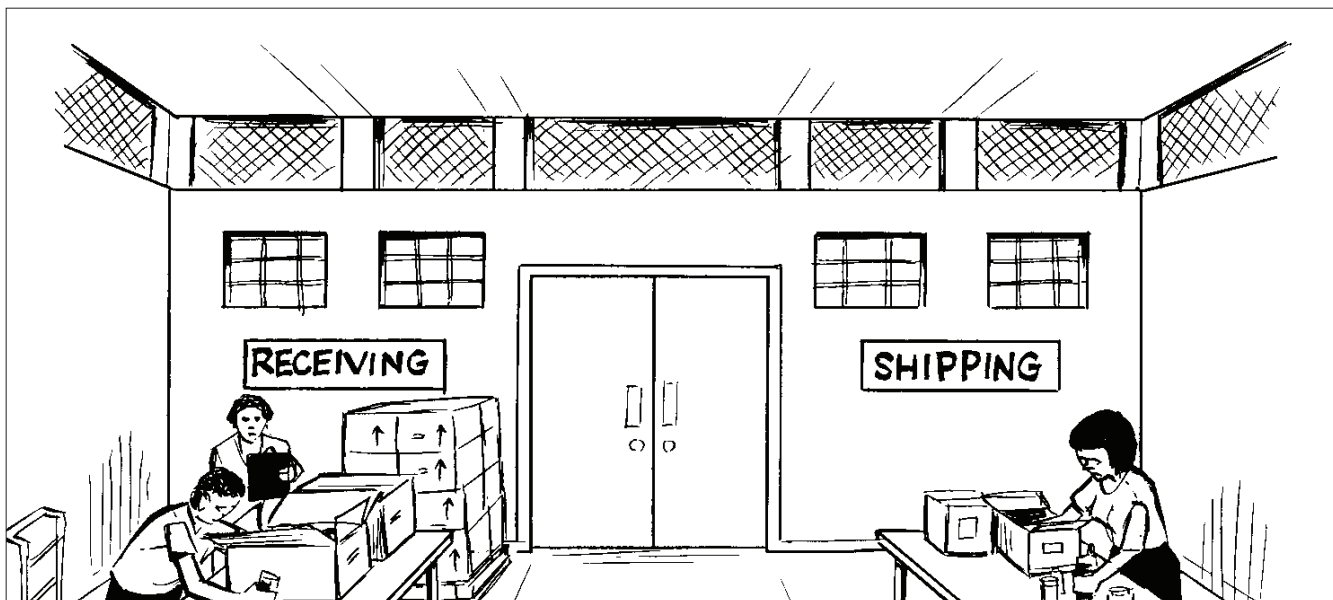
The cost of removing unwanted medicine can be as high as buying the same medicine.

Even a little communication between donor and recipient will make an improvement in the appropriateness of the donation.



Credit: HAI Africa

A worker offloads medicines from a truck



Credit: John Snow, Inc./DELIVER & WHO

Shipping and receiving medicine donation

Guidelines for medicine donations

A. Selection of medicines

1. All donations should be based on an expressed need and be relevant to the disease pattern in the recipient country. Medicines should not be sent without prior consent by the recipient.

Justification and explanation

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.

Possible exceptions

In acute emergencies the need for prior consent by the recipient may be waived, provided the medicines are amongst those from the WHO Model List of Essential Drugs that are included in the UN list of emergency relief items recommended for use in acute emergencies.

2. All donated medicines or their generic equivalents should be approved for use in the **recipient** country and appear on the national list of essential medicines, or, if a national list is not available, on the WHO Model List of Essential Medicines, unless specifically requested otherwise by the recipient.

Justification and explanation

This provision is intended to ensure that donations comply with national drug policies and essential medicines programmes. It aims at maximizing the positive impact of the donation, and prevents the donation of medicines which are unnecessary and/or unknown in the recipient country.

Possible exceptions

An exception can be made for medicines needed in sudden outbreaks of uncommon or newly emerging diseases, since such medicines may not be approved for use in the recipient country.

3. The presentation, strength and formulation of donated medicines should, as much as possible, be similar to those of medicines commonly used in the recipient country.

Justification and explanation

Most staff working at different health care levels in the recipient country have been trained to use a certain formulation and dosage schedule and cannot constantly change their treatment practices. Moreover, they often have insufficient training in performing the necessary dosage calculations required for such changes.

B. Quality assurance and shelf-life

1. All donated medicines should be obtained from a reliable source and comply with quality standards in both donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.

Justification and explanation

This provision prevents double standards: medicines of 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 Good Manufacturing Practice (GMP).

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 the donor.

Guidelines for medicine donations

When donors provide funds to purchase medicines from local producers, those which comply with national standards should not be excluded on the sole grounds that they do not meet quality standards of

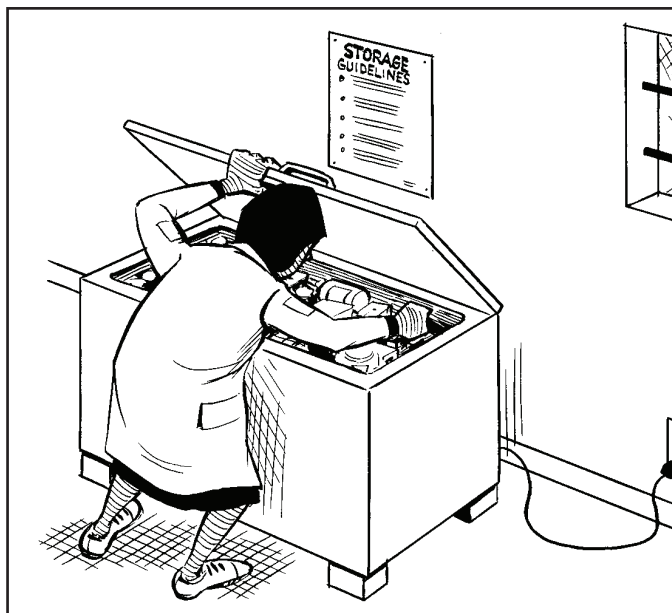


the donor country.

2.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.

Justification and explanation

Patients return unused medicines to a pharmacy to ensure their safe disposal; the same applies to samples that have been received by health workers. In most countries it is not allowed to issue such medicines to other patients, because their quality cannot be guaranteed. For this reason returned medicines



should not be donated either. In addition to quality issues, returned medicines are very difficult to manage at the receiving end because of broken packages and the small quantities involved.

3.After arrival in the recipient country all donated medicines should have a remaining shelf-life of at least one year. An exception may be made for direct donations to specific health facilities, provided that: 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 recipient well in advance.

Justification and explanation

In many recipient countries, and especially under emergency situations, there are logistical challenges. Very often the regular distribution system has limited possibilities for immediate supply. Regular distribution through different storage levels (e.g. central store, provincial store, district hospital) may take six to nine months. This provision especially prevents the donation of medicines just before their expiry, as in most cases such medicines would only reach the patient after expiry.

Note: Overstocking may lead to wastage. The argument that short-dated products can be donated in the case of acute emergencies, because they will be used rapidly, is incorrect.

Additional exception

Besides the possible exception for direct donations mentioned above, an exception should be made for medicines with a total shelf-life of less than two years, in which case at least one-third of the shelf-life should remain.

C. Presentation, packing and labelling

1. All medicines should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Nonproprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.

Justification and explanation

All donated medicine, including those under brand name, should be labelled also with their INN or the official generic name. Most training programmes are based on the use of generic names. 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.

2. As much as possible, medicines should be presented in larger quantity units **and hospital packs**.

Justification and explanation

Large quantity packs are more affordable, less bulky to transport and conform better with public sector supply systems in most developing countries. This provision also prevents the donation of medicines in sample packages, which are impractical to manage.

3. All 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 INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 50 kilograms. Medicines should not be mixed with other supplies in the same carton.

Justification and explanation

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- and labour-intensive. This provision specifically discourages donations of small quantities of mixed drugs.

Medicine expiry dates



Credit: http://www.nps.org.au/_data/assets/image/0007/170756/autumn09p4_web.gif



Photo Credit: EPM

Workers inspecting donated medicines

D. Information and management

1. Recipients should be informed of all donations that are being considered, prepared or actually underway.

Justification and explanation

Many donations arrive unannounced. Detailed advance information on all donations is essential to enable the recipient 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 INN or generic name,

appropriate storage and handling should be paid for by the donor agency, unless specifically agreed otherwise

strength, dosage form, manufacturer and expiry date; reference to earlier correspondence (for example, the letter of consent by the recipient); the expected date of arrival and port of entry; and the identity and contact address of the donor.

2. The declared value of a donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.

Justification and explanation

This provision is needed solely to prevent donations being valued in the recipient country according to the retail price of the product in the donor country. This may lead to elevated overhead costs for import tax, port clearance and handling in the recipient country. It may also result in a corresponding decrease in the public sector medicines budget in the recipient country.

Possible exception

In the case of patented medicines for which there is no generic equivalent the wholesale price of the nearest therapeutic equivalent could be taken as a reference.

3. 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 the recipient in advance.

Justification and explanation

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

Summary of National Guidelines for receiving medicines donations

Below is a concise summary to act as a reminder.

1. Implementation of a National Guidelines

A national guideline should be drawn up by the recipient country according to international guidelines and should be officially implemented so that donors can follow closely and donate according to the needs of the country.

2. Implementation of Administrative Procedures

This involves aligning of donations with proper paperwork procedures and appointing administrative staff to receive donations.

3. Stating Specific Medicine Needs

The recipient should advise the donor on what medicines are needed specifically.

4. Medicines that expire within a year

WHO recommends that donors should send medicines that have at least a year of shelf life left before they expire. An exception to this however, is donation of medicine to specific health

facilities, where a health professional agrees and is aware of the short expiry, and knows that the medicine will be used quickly.

5. Quick Custom Clearance

Donated medicines should clear customs rapidly according to strict national guidelines. Those that fall short of the guidelines should be rejected immediately. This would allow quick and proper aid to recipients.

6. Donated Medicines Management

Medicines that are received should be checked and stored properly and securely by trained staff adhering to proper pharmacy practice. The recipients should notify the donors when medicines are received, after which they can be distributed to appropriate health facilities.

In conclusion, if donors and recipients work hand in hand in simple procedures, such as those above, there will be a significant decrease in medicines wastage. Donations will reach those who really need them and not fall into misuse. Below is a checklist that might assist those handling donations.

Checklist for Receiving Medicines Donations

Has a national guideline been implemented?	
Has appropriate and trained staff been appointed for the receiving of medicines?	
Have you specified what medicines are needed to the donor?	
Is there an appropriate shelf life and quality on the medicines received?	
Are medicines that do not follow the national guidelines rejected?	
Are donated medicines managed by proper pharmacy practice?	
Have donated medicines reached the designated health facilities?	

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Guidelines for receiving donations are available at: www.euro.who.int/document/EHA/PAR_Donate_Guidelines.pdf

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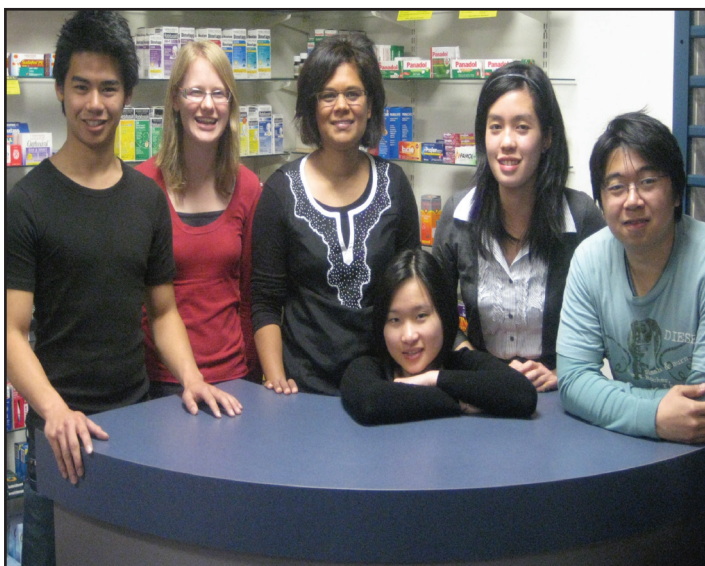
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This quarters contributors: (From left) Chin-Hoe (Rick) Tan; Jasmin Dodge; Aarti Patel; Guan Yi (Krystal) Chan; Adrene Giam and Xianzhi (Daniel) Heng. The second picture: Pharmacy lecturer University of Otago and HAI Africa board member Aarti Patel during her PHD graduation in New Zealand in 2009. She attained a Phd in exploring the issue of quality of medicines in South Africa.