Guidelines for Medicine Donations

National Medicines Regulatory Authority
Ministry of Health, Sri Lanka

1. Introduction

These Sri Lankan guidelines are based on the Guidelines for Medicine Donations developed by the World Health Organization (WHO) and revised in 2010. There are many different scenarios for medicine donations, such as emergency aid, long-term aid, or assistance to national health systems or to individual health facilities. Donations may come from pharmaceutical companies (directly or through private voluntary organizations), they may come in the form of aid from governments, or they may be donations aimed directly at single health-care facilities. The intended beneficiaries of donations of medicines range from individual facilities to entire health systems.

2. The need for guidelines

Although there are legitimate differences between these scenarios, many basic rules for appropriate donation practice apply to all. The guidelines aim to describe this common core of good medicine donation practice.

Unfortunately, there are many examples of medicine donations that have caused problems instead of bringing relief. A sizeable disaster does not always lead to an objective assessment of the need for health products, and emotional appeals for large-scale medical assistance may be issued without guidance as to what the priority needs are. The example below is a good experience of inappropriate medicine donations.

Sri Lanka, Tsunami, 2004

Although Sri Lanka adhered to the WHO guidelines regarding expressing need for selected medicines, donors failed to comply with guidelines related to quality assurance and shelf-life, presentation, packaging and labelling, or information management. Following the tsunami, there was medical assistance from 278 donors, including 98 local organizations and non-governmental organizations, 150 international organizations and 30 foreign governments. Immediate relief was obtained from buffer stocks and local donations. Although the Ministry of Health issued a needs-based list of requested medications, there were large amounts of inappropriate donations and the appropriate donations arrived in excess. Of the 56 tons received, only 10% were on the list of requested medications. More than 80% were unsolicited, unexpected and unsorted. Forty-three percent of donated medicines were not essential medicines and 38% were never registered for use in the country. Labelling was inappropriate with 62% labelled in languages not readily understood, 15% without generic names and 81% without package inserts. Fifty percent of donations did not have an expiry date; 6.5% expired on arrival and 67% expired within less than a year. Donations were largely uncoordinated with 50% from collections of unused drugs from private donors and 86% of donations donated by individuals. In contrast, 90% of government

DRAFT

donations were relevant. Due to the excess donations, more than 20-30 tons of drugs were inappropriately stored. Also, the large quantity of donations required renting of storage sites or use of a variety of facilities that had inappropriate storage conditions to maintain drug quality. Improper storage of spinal anaesthesia remaining from donation may have allowed for contamination by *Aspergillus sp*, resulting in nosocomial meningitis and the death of 3 pregnant women in 2005. The excess of donations strained human resources in areas of receiving, processing and distribution. Some financial donations were equivalent to 50% of the Sri Lankan health budget but were spent on expensive drugs manufactured outside the region. The Sri Lankan Ministry of Health supported the costs of handling, transport and storage of donations, as well as the cost for destroying 150 metric tons of medicines at US$ 120-180 per ton[1].

3. Guidelines for medicine donations

3.1 Selection of medicines

(a) All medicine donations should be based on an expressed need, should be relevant to the disease pattern in Sri Lanka. Medicines should not be sent without prior clearance by the Ministry of Health.

Justification and explanation

It is the prime responsibility of the recipient for specifying needs. This implies that there should be a clear agreement on which the donation of medicines should be based. The recipient should also be responsible for determining the quantities of products to be donated since appropriate quantification of needs is an important component of quality donations. Unsolicited, unwanted or unneeded donations should not be made, as they may lead to over-stocking and expiry of donated products. There should be cooperation between the donor and the recipient from the initiation of the donation, through its planning, and until the final shipment.

(b) All donated medicines or their generic equivalents should be approved for use in Sri Lanka and should appear on the National Essential Medicines List unless specifically requested otherwise and provided with a justification by the recipient.

Justification and explanation

Medicine donations must comply with the National Medicines Policy, National Essential Medicines List and National Treatment Protocols.

Possible exceptions

An exception can be made for medicines needed in sudden outbreaks of uncommon or newly emerging diseases and rare diseases because such medicines may not be registered in Sri Lanka.

DRAFT

(c) The presentation, strength, and formulation of donated medicines should, as far as possible, be similar to those of medicines commonly used in Sri Lanka.

Justification and explanation

Staff at the different levels of health care are familiar with certain formulations and dosage schedules and should preferably not be confronted with other treatment practices. Moreover, dosage recalculations may introduce medication errors.

Quality assurance and shelf-life

(d) All donated medicines should be obtained from a quality-ensured source and should comply with quality standards in both donating country and Sri Lanka. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce may be used.

Justification and explanation

Double standards should be prevented. Medicines of unacceptable quality in the donor country should not be donated to Sri Lanka. Donated medicines should be authorized for sale in the country of origin and should be manufactured in accordance with international standards of good manufacturing practices (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.

(e) Medicines that have been issued to patients and then returned to a pharmacy or elsewhere, or that have been given to health professionals as free samples should not be donated.

Justification and explanation

The re-issue of medicines is not permitted as the quality cannot be guaranteed. In addition, returned medicines are difficult to manage because of broken packages and the small quantities involved. Free samples given to health professionals should not be further distributed as donations.

(f) After arrival in Sri Lanka all donated medicines should have a remaining shelf-life of at least one year. Large quantities of donated medicines become a logistical challenge, even with a long shelf-life. Therefore, based on the national consumption and available quantities in stock or in the supply chain pipeline, all donated quantities should match the needs to be consumed before they are expired.

DRAFT

Justification and explanation

In many recipient countries, especially in emergency situations, logistical problems exist. Regular medicine distribution systems often have limited possibilities for immediate distribution, and distribution through the different storage levels (e.g. central MSD, regional MSD and health facilities) 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

An exception could be made for medicines manufactured with a short shelf-life of less than one year because of their physical properties. Vaccines demand stringent conditions during storage and distribution. They should only be donated in close collaboration with the Medical Supplies Division of the Ministry of Health, Sri Lanka and on agreement that the stock of medicine can be utilized for patients before it expires.

3.2 Presentation, packaging and labelling

(a) all medicines should be labelled in the English language. The label on each container should contain at least the International Nonproprietary Name (INN) or generic name and the following:

(i) Batch number
(ii) Dosage form
(iii) Strength
(iv) Name of manufacturer
(v) Country of manufacture
(vi) Total quantity in the container
(vii) Storage conditions
(viii) Date of manufacture and Date of expiry
(ix) All medicines should be accompanied by prescriber information in the English Language
(x) In the case of injections, the route of administration should be indicated.

Justification and explanation

Sri Lanka health system operates on the basis of generic names. All donated medicines, including those under a brand name, should therefore be labelled also with their INN or generic name. Receiving medicines under different and often unknown brand names or without the INN is confusing and can be dangerous for patients.

(b) As far as possible donated medicines should be presented in large packs and hospital packs. Donations of paediatric cough syrups and or mixtures are discouraged. Wherever possible, paediatric medicines should preferably be in solid form, e.g. dispersible tablets, and not liquid formulations because of their more demanding logistical needs.

DRAFT

Justification and explanation
Large quantity packs (for example, tins of 1000 tablets) are cheaper and could be easier to transport. This also prevents the donations of medicines in sample packages, which are not practical to manage. In general, paediatric formulations in solid dose form are less costly to handle in terms of storage and transport costs and logistics management.

(c)All medicine donations should be packed in accordance with international shipping requirements and should be accompanied by a detailed packing list that 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 preferably not exceed 30 kilograms. Different medicines should not be packed together in one carton and medicines should not be mixed with other supplies.

Justification and explanation
Easy administration, storage and distribution of donations is important, as the identification and management of items in unmarked boxes with mixed medicines and/or supplies is time-consuming and labour-intensive. The maximum weight of 30 kilograms ensures that each carton can be handled without special equipment.

3.3 Information and management

(a) Medicine donations should be jointly planned, and collaboration between donors and the Ministry of Health, Sri Lanka should begin early. Medicines should not be sent without prior consent of the Ministry of Health, Sri Lanka.

Justification and explanation
Detailed advance information on medicine donations is essential to allow for planning of receipt and coordination of the donations with other sources of supply. Information provision is part of the donor's responsibility. Information should be made available well in advance in order to allow for smooth customs clearance and further distribution of products to end-users. 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.

(b) The declared value of medicine donations should be based on the wholesale price of its generic equivalent in Sri Lanka the 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 medicine donations from being valued in Sri Lanka according to the retail price of the product in the donor country – which can lead to elevated

DRAFT

overhead costs for import tax, port clearance and handling. It may also result in a corresponding decrease in the public sector medicine budget in the 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.

(c) **Costs of international and local transport, warehousing, port clearance and (customs) storage, handling and disposal or reverse logistics of expired donated products should be paid for by the donor agency, unless specifically agreed otherwise with the Sri Lankan Authorities in advance.**

Justification and explanation

Recipients should be prevented from being forced to spend effort and money on customs storage, clearance and further transport of unannounced or unwanted donated medicines.

(d) Similarly, the cost of disposing of a medicine donation adjudged to be unsuitable should be borne by the donor. Donors are requested to fill in the donation form (Annex 1) annexed with these guidelines prior shipment of goods and submit it to the Secretary of the Ministry of Health, Sri Lanka.

Justifications and explanation

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

References:

1. Benaragamama BVSH, Fernandopulle R. The expectations, the reality and the burden of drug donation. Colombo, Ministry of Healthcare and Nutrition, Sri Lanka and Faculty of Medicine, University of Colombo, 2007. Available at: http://www.health.gov.lk/msd_publication.html

DRAFT