



*Australian
guidelines
for drug
donations
to developing
countries*

**Endorsed by the Australian
Pharmaceutical Advisory
Council
November 1996**

Amendments endorsed
November 2000



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Introduction

These Australian guidelines are based on the international Guidelines for Drug Donations developed by the World Health Organisation (WHO) in 1996. The WHO's guidelines reflect a consensus between the major international agencies active in humanitarian emergency relief: WHO, Office of the United Nations High Commission for Refugees (UNHCR), United Nations Children's Fund (UNICEF), International Committee of the Red Cross, Medecins sans Frontieres, Churches Action for Health and the World Council of Churches. They aim to improve the quality of drug donations and are intended to serve as a basis for national and institutional guidelines.

Scenarios associated with drug donations range from acute emergencies to non-emergency development programs. Although there are differences between these scenarios, there are basic rules for an appropriate response that apply to all.

As with the guidelines prepared by WHO, this Australian document starts with a discussion on the need for guidelines, followed by the presentation of the core principles for appropriate donations.

The Australian guidelines have been endorsed by the Australian Pharmaceutical Advisory Council (APAC). APAC expresses its appreciation to the Society of Hospital Pharmacists of Australia for its assistance in developing these guidelines.

Why do we need guidelines for donations of drugs to developing countries?

The contribution of medicines in the form of donations to developing countries or in disaster situations is often viewed by communities in developed countries, such as Australia, as a useful way to provide much needed pharmaceutical supplies. Televised pictures of refugee camps or rural areas lacking the most basic health services often give rise to emotional appeals to 'do something'. As the lack of medicines is often presented as a pressing problem, an immediate donation of drugs is often perceived as the most pragmatic and direct response. Unfortunately not all drug donations are helpful and inappropriate drug donations can be dangerous or useless, and a source of problems for the recipients as the following examples illustrate.

Guatemala, 1976

In the first week after the earthquake in Guatemala, 7000 cartons of mixed drugs arrived. These were sorted by a group of 40 pharmacy students at a rate of 25-50 boxes per day (it took about six months to finish the job). Only 10% of the drugs sent were relevant to the health needs in Guatemala and were adequately labelled.

Sudan, 1990

A large consignment of drugs was sent from France to war-devastated southern Sudan. Each box contained a collection of small packets of drugs, some partly used. All were labelled in French, a language not spoken in Sudan. Most were inappropriate, some could be dangerous. There were: contact lens solutions, appetite stimulants, antidepressants and expired antibiotics. Of 50 boxes, 12 contained drugs of some use. It would have been much better to use the money spent on transport to purchase penicillin and other essential drugs from Kenya and to have them sent from there.

Eritrea, 1980s

During the war for independence, despite careful wording of appeals, much time and energy had to be spent on sorting drug consignments. Examples of inappropriate donations were: seven truck loads of expired aspirin tablets that took six months to burn; a whole container of unsolicited cardiovascular drugs with two months to expiry; and 30,000 half-litre bottles of expired amino-acid infusion that could not be disposed of anywhere near a settlement because of the smell.

How else can drug donations cause problems?

Most developing countries have national essential drugs lists covering major health problems. Training programs for health personnel focus on the correct use of these drugs. Such developments need support. Donated drugs can frustrate and undermine national drug policies which aim to secure reliable supplies of appropriate, good quality, essential drugs and to promote standard treatment guidelines as a tool to encourage rational drug use.

There are also problems with the quality of donated drugs, donation of expired drugs being a common practice. This practice is not acceptable. If the quality of a drug is not suitable for use in Australia, it is not suitable for donation to an overseas country.

Apart from the issues of the quality of the products, eg expired/damaged drugs, and the relevance of the drugs to the situation, logistical difficulties can also arise. These difficulties are associated with sorting, storage and distribution which may waste valuable human and financial resources. In addition, transport costs may be higher than the value of the drugs, and local purchase can be more cost effective.

Guidelines for donating drugs

Core principles

- A donation is intended to assist the recipient. Donations should be based on an expressed need. Donor-initiated donations where the recipients advice has not been sought are unhelpful.
- Donations must support essential drug policies. Respect must be given for the authority of the recipient and the receiving country s administrative arrangements.
- There should be no double standards. If the quality of an item is not acceptable in Australia it is unacceptable as a donation. Therefore the collection and redistribution of patients unused medicines is not permitted.

Selection of drugs

1. All drug donations should be based on an expressed need.
 - Drugs should not be sent without prior clearance by the recipient.
 - A written request should be obtained from a competent authority in the recipient country.
 - The health facility receiving the drugs should be required to acknowledge receipt of the donated medicines.

Justification

This provision excludes donor-driven donations, or donations which arrive unannounced and unwanted. It encourages recipients to specify their needs, and empowers them to refuse unwanted gifts.

2. All donated drugs should be on the national list of essential drugs of the recipient country or, if such a national list is not available, on the WHO Model List of Essential Drugs.

Justification

This provision ensures that drug donations comply with existing government policies and with the essential drugs concept. It aims at maximising the positive impact of the donation, and excludes the donation of unnecessary or dangerous drugs, and drugs which are not specified for use in that country.

Copies of the WHO Model List of Essential Drugs are available from Hunter Publications, 58 Gipps Street, Collingwood, 3066. Telephone: 03 9417 5361.

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

Justification

Most staff working at different health care levels in the recipient country have been trained to use a certain dosage schedule and dosage forms. Treatment guidelines cannot be constantly changed.

Note: Vaccine donations

The donation of vaccines is not appropriate because of the logistical problems associated with transport and storage. Donations of money for purchasing vaccines are more helpful, so cold chain facilities can be put in place, and the right quantity and type of vaccine and associated supplies can be ordered at the right time. Donations for vaccine purchase should only be directed to a responsible agency which has an accepted role in immunisation programs such as Australian Red Cross, Medecins Sans Frontieres, UNICEF, Save The Children Fund and World Vision Australia.

Quality and shelf-life

4. All donated drugs should comply with quality standards in both the donor and recipient country.

Justification

This provision prevents double standards. For example, donations of unused drugs (returned drugs from patients or doctors free samples), which would not be acceptable for use in Australia should not be donated to another country.

5. All donated drugs should have a remaining shelf-life of at least one year after the arrival in the recipient country, with an exception for direct donations to a specific health program in response to an urgent and special request. This exception may be made provided; the date of arrival and the expiry dates of the drugs is advised to the responsible recipient professional, and that they acknowledge that they are aware of the shelf-life; and, that prior to expiration, the quantity and remaining shelf-life allow for proper administration.

Justification

Considerable periods of time may elapse before donated drugs are transported, cleared through customs, relocated to a warehouse, contents identified and recorded, and the drugs dispatched to the place of use. Distribution may take many months as drugs are moved from a central store, to provincial stores, to district hospitals and other peripheral health facilities. Very few possibilities for immediate distribution exist.

Presentation, packing and labelling

6. All drugs should be labelled in a language that is easily understood in the recipient country. The label should contain at least the International Non-proprietary Name (generic name), dosage form, strength, name of manufacturer, storage conditions and expiry date.

Product Information and Consumer Product Information (where available) should be included for each of the drugs sent.

Justification

Generic names can be understood in any country where Roman script is being used. Training programs are based on the use of generic names. Receiving the same drug under many different and often unknown brand names is very confusing to the health workers and can even be dangerous. The use of generic names also prevents brand-name loyalty being inadvertently promoted by the donor.

Many health facilities in developing countries do not have access to current, complete and accurate drug information. Where national treatment guidelines are not in use, it is important that prescribers and dispensers are provided with this information to ensure safe use.

7. As much as possible, donated drugs should be presented in larger quantity units.

Justification

Larger quantity packs are more cost-effective as they are cheaper and less bulky to transport. This should not be taken as encouragement to repack drugs from different batch lots and expiry dates into one container.

Export and transport

8. All drug donations should be packed in strong outer cartons and be accompanied by a detailed packing list which should specify the contents of each carton by generic name, quantity and expiry date. Cartons should be numbered and the contents of each carton listed in detail in the accompanying documents. In addition, the contents of cartons should be marked on the outside of cartons, preferably using a code system.

Justification

In addition to knowing what is coming the recipient is assisted when the consignment arrives. S/he will know just where to find items which may be needed urgently (instead of having to unpack the

whole shipment) and will be able to decide where to direct items that may be intended for different centres. A code numbering system for listing contents on the outside of packs is better than the use of the names of items which can facilitate pilferage.

9. Preparation for consignment of goods must be undertaken in close co-operation with the recipient to determine the transport and clearance arrangements, documents needed by the recipient, and the costs that need to be met by the donor. The recipient will require advance details of the content of the shipment and its time of arrival. In most cases international transport, customs warehousing, clearance costs and internal transport will need to be paid by the donor. However, in some cases the recipient is able to cover the cost of clearance and internal transport. Agencies should make their own arrangements to comply with customs documentation requirements at all dispatch, transit and entry points.

Justification

The recipient will know the local requirements for receiving and clearing consignments and will be able to make preparatory arrangements for prompt clearance in advance. It is most important that shipments are met on arrival. Having a consignment lying on the docks or in a store somewhere, without attention, is also potentially disastrous, and can be very expensive. In addition, these provisions prevent the recipient having to spend effort and money on the clearance and transport of unannounced consignments of unwanted items and enables the recipient to review the list of donated items at an early stage. However, it does not exclude costs being paid by the recipient, if prior notice has been given and agreement has been reached.

Federal Permits

10. The export of certain drugs, including drugs of addiction, ie, drugs listed in Schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons, psychotropic substances such as stimulants, barbiturates and benzodiazepines as well as drugs and chemicals of concern such as ephedrine and pseudoephedrine, requires a written permission to export from the Australian Government Department of Health and Ageing. This written permission must be obtained prior to the shipment leaving Australia. Special conditions apply to the issue of a written permission to cover an immediate response to an emergency situation. The person responsible for shipping the donation should contact –

Therapeutic Goods Administration
The Treaties and Monitoring Team
PO Box 100
WODEN ACT 2606

Telephone: (06) 6270 4331
Facsimile: (06) 6270 4325

– with a list of drugs proposed to be donated, to confirm whether a licence and export permit is required.

If the items do not require an export permit, and provided the drugs have been legally acquired within Australia, are not for commercial supply and are not intended for use in clinical trials, there is no requirement to provide any documentation to the Federal authorities.

How can Australians help?

The most appropriate response to appeals for help or ongoing assistance to developing countries is a financial contribution.

It is usually cheaper for drugs to be purchased locally, or from specialist non-profit procuring agencies which are closer to the scene. Local procurement, which involves only a fraction of the transport costs, encourages locally sustainable drug availability and support for local industry is a more development oriented approach. Provision of funds for direct procurement from specialist non-profit agencies such as IDA - International Dispensary Association, is the most helpful strategy when supplies are not available locally.

In emergencies, the most appropriate action may be the purchase of the World Health Organisation Emergency Health Kits which include drugs and medical supplies for a population of 10,000 people for a period of three months. Delivery within 48 hours can be arranged through:

1. IDA - International Dispensary Association,
PO Box 37098
1030 AB Amsterdam
THE NETHERLANDS

Telephone: 31-20-403-3051
Facsimile: 31-20-403-1854
E-mail: ida_sale@euronet.nl
or
2. UNICEF - United Nations Children's Fund
Unicef Plads - Freeport
DK-2100 Copenhagen 0
DENMARK

Telephone: (35)-273527
Facsimile: (35)-269421
Telex: 19813

Donations of funds for purchase of these kits can be very helpful.

Donors wishing to identify the coordinating agency for a current emergency can find information on the Internet (World Wide Web) under United Nations Departments UNDHA - UN Department of Humanitarian Affairs:

UNDHA <http://www.un.org/Depts/dha/>

Relief <http://www.reliefnet.org/>

Alternatively information can be sought from:

- Medical Advisor, Australian Red Cross National Office, telephone 03 9418 5200,
- Medical Advisor, Medecins sans Frontieres, National Office, telephone 02 9319 3500;
- Emergency Program Officer, AusAID Human Relief Programs, telephone 062 064586.

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