

## Guidelines for drug donations<sup>1</sup>

When there is a natural disaster or some other major catastrophe, many people want to reach out and help those in need. Medicines are a key element in relieving suffering, and international humanitarian relief efforts can greatly benefit from donations of appropriate drugs, whether in response to an acute emergency or as part of an ongoing program of development aid.

Unfortunately, in some cases those contributions may cause more problems than good. That was true, for example, with some of the drug donations made after a major earthquake struck Mexico City in 1985. Following the earthquake in Armenia in 1988, the volume of donated drugs and medical supplies far exceeded the need. Eight percent of the drugs were expired on arrival, and 4% more were destroyed by frost. Of the remainder, only 30% were easy to identify and only 42% were relevant for an emergency situation. The majority of the drugs were only labeled with brand names, rather than their International Nonproprietary Name or generic name, on which most medical and pharmaceutical training programs are based.

There have been similar incidents in more recent years as well. A World Health Organization (WHO) audit of humanitarian drug donations received in Albania during May 1999 for Kosovo refugees showed that as much as half of those drugs were inappropriate or useless, and would have to be destroyed. Sixty-five per cent of drugs were either missing an expiry date or were due to expire less than one year from the date of donation.

To deal with those kinds of difficulties, the World Health Organization has worked with a number of other organizations to create guidelines on appropriate drug donations. First published in 1996, those WHO guidelines were recently updated and reissued by WHO on behalf of more than a dozen other organizations that helped to revise the earlier recommendations.

Rather than impeding drug donations, the guidelines are intended to improve the quality of such contributions. And instead of being international regulations, the guidelines are designed to serve as a basis for national or institutional guidelines that governments and organizations dealing with drug donations can review, adapt, and implement.

The twelve WHO guidelines fall into four major areas: selection of drugs; quality assurance

<sup>1</sup> Based on: World Health Organization, Department of Essential Drugs and Other Medicines. Guidelines for drug donations. 2nd edition. Geneva: WHO; 1999. Available from: <http://www.who.int/medicines/docs/edmguidelines.html>. Accessed 24 January 2000.

and shelf life; presentation, packing, and labeling; and information and management.

## SELECTION OF DRUGS

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

This provision stresses the point that it is the prime responsibility of recipients to specify their needs. This helps prevent unsolicited donations and donations that arrive unannounced and unwanted.

As with several of the WHO guidelines, there may be exceptions to this recommendation, based on local conditions. For example, in an acute emergency the need for the recipient's prior consent may be waived, provided the drugs are on the WHO Model List of Essential Drugs and are included in the United Nations' list of emergency relief items recommended for use in acute emergencies.

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

This recommendation is intended to maximize the positive impact of the donation and prevent the donation of drugs which are unnecessary and/or unknown in the recipient country. An exception can be made for drugs needed in sudden outbreaks of uncommon or newly emerging diseases, since such drugs may not be approved for use in the recipient country.

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

Most personnel working at different health care levels in the recipient country have been trained to use a certain formulation and dosage schedule; they should not be forced to constantly change their treatment practices.

## QUALITY ASSURANCE AND SHELF LIFE

4. *All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country.*

This provision prevents such "double standards" as drugs of unacceptable quality in the

donor country being donated to other countries. Donated drugs should be authorized for sale in the country of origin and manufactured in accordance with international standards of "good manufacturing practice."

5. *No drugs 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.*

Because the quality of such returned drugs cannot be guaranteed, they should not be donated. Returned drugs are also very difficult to manage at the receiving end because of broken packages and the small quantities involved.

6. *After arrival in the recipient country all donated drugs should have a remaining shelf life of at least one year.*

In many recipient countries, and especially under emergency situations, there are logistical problems, with the regular drug distribution system having more limited capacity. Regular distribution through different storage levels (e.g., central store, provincial store, district hospital) may take six to nine months.

An exception on shelf life may be made for direct donations to specific health facilities, provided that the responsible professionals at the receiving end acknowledge that they are aware of the shelf life and that the quantity and remaining shelf life allow for proper administration prior to expiration.

## PRESENTATION, PACKING, AND LABELING

7. *All drugs should be labeled 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. Receiving drugs under different and often unknown brand names and without the INN is confusing for health workers and can even be dangerous for patients.

8. *As much as possible, donated drugs should be presented in larger quantity units and hospital packs.*

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

9. *All drug donations should be packed in accordance with international shipping regulations and accompanied by a detailed packing list, with the weight per carton not exceeding 50 kilograms.*

This recommendation facilitates the administration, storage, and distribution of donations in emergency situations, given that the identification and management of unmarked boxes with mixed drugs is very time- and labor-intensive work. This provision specifically discourages donations of small quantities of mixed drugs. The weight limit ensures that each carton can be handled without special equipment.

## INFORMATION AND MANAGEMENT

10. *Recipients should be informed of all drug donations that are being considered, prepared, or actually under way.*

Detailed advance information on all drug donations enables the recipient to plan for the receipt of the donation and to coordinate the donation with other supply sources.

11. *In the recipient country the declared value of a drug 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.*

This provision prevents drug donations from being valued in the recipient country according to the product's retail price there, which could lead to elevated overhead costs for import tax, port clearance, and handling in the recipient country. Overvaluing drug donations may also result in a corresponding decrease in the public sector drug budget in the recipient country.

12. *Costs of international and local transport, warehousing, port clearance, and appropriate storage and handling should be paid by the donor agency.*

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

## IMPLEMENTING A NATIONAL POLICY ON DRUG DONATIONS

Careful local planning and implementation by donor recipients can increase the effectiveness of the WHO guidelines.

Working from the international guidelines, recipients should first formulate their own national guidelines for drug donations. These local guidelines can be included in the national drug policy. The national guidelines should be officially presented and explained to the donor community. Only after they have been presented and officially published can they be enforced.

Recipients must also develop administrative procedures to maximize the potential benefit of drug donations. As much as possible, such arrangements should be linked with existing drug supply systems. Among the key issues that should be decided and then included in such administrative procedures are:

- who is responsible for defining the needs, and who will prioritize them
- who coordinates all drug donations
- which documents are needed when a donation is planned and who should receive them
- procedures to be used when donations do not follow the guidelines
- the criteria for accepting or rejecting a donation, and who makes the final decision
- who coordinates reception, storage, and distribution of the donated drugs
- how donations are valued and entered into the budget and expenditure records
- how inappropriate donations will be disposed of

A third key step is for recipients to specify the needs for donated drugs as much as possible, indicating the required quantities, priorities, and other donations that are already in the pipeline or anticipated.

Recipients should also work to ensure the rapid customs clearance of donated drugs. Customs and health ministry officials should allow the entry of useful donations while rejecting short-dated donations for which satisfactory distribution provisions have not been made.

Recipients should treat donated drugs with due attention and care. On arrival the drugs should be inspected and their receipt confirmed to the donor agency. The drugs should then be stored and distributed in accordance with normal principles of good pharmacy practice, and under the responsibility of adequately trained professionals. There must be due vigilance to ensure that donated products are not diverted for export, commercial sale, or into illicit channels.

Within a recipient country, the different donors should establish a coordinating body, especially in emergency situations. This body should help determine the needs, priorities, storage, logistics, and distribution, as well as serve as the central

contact point in discussions with the recipient government authorities.

Donor countries can also work to make the general public in their countries aware of past problems with drug donations and of the preferred standards for such contributions, such as by trying to have that information included in media news reports and appeals for assistance.

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SINOPSIS

### **Directrices para la donación de medicamentos**

*Las donaciones de medicamentos pueden desempeñar un papel esencial en la ayuda tras desastres naturales o como*

*parte de programas de cooperación internacional para el desarrollo. No obstante, cuando son mal manejadas pueden resultar inadecuadas y causar más problemas que los que resuelven. Estas directrices revisadas y actualizadas de la Organización Mundial de la Salud describen las “prácticas de donación adecuadas” que permiten mejorar la calidad de las donaciones de medicamentos. Como base para la elaboración de directrices nacionales o institucionales, pueden ser adaptadas y puestas en práctica por los gobiernos y organizaciones que se ocupan de las donaciones de medicamentos. Las 12 directrices abordan problemas como la selección de los fármacos; la garantía de calidad y la caducidad; la presentación, envasado y etiquetado, y la información y gestión.*

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