INTERAGENCY GUIDELINES

Guidelines for Medicine Donations

Revised 2010

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Revised 2010

World Health Organization (WHO)

Ecumenical Pharmaceutical Network (EPN)

International Pharmaceutical Federation (FIP)

International Federation of Red Cross and Red Crescent Societies

International Health Partners

The Partnership for Quality Medical Donations (PQMD)

United Nations Development Programme (UNDP)

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1. Introduction

This 3rd edition of *Guidelines for medicine donations* has been developed by the World Health Organization (WHO) in cooperation with major international agencies active in humanitarian relief and development assistance. The guidelines are intended to improve the quality of medicine donations in international development assistance and emergency aid. Good medicine donation practice is of interest to both donors and recipients.

The 1st edition of the guidelines (then titled *Guidelines for drug donations*) was published in May 1996 and represented the consensus of WHO and a variety of international relief and development agencies. The 1st edition was based on several rounds of consultation with over 100 humanitarian organizations and individual experts. A thorough evaluation of the 1st edition formed the basis of the 2nd edition of the guidelines published in 1999. The 2nd edition received support from an expanded group which included nongovernmental organizations (NGOs) in international development, umbrella organizations of the pharmaceutical industry, several United Nations agencies, and the World Bank. The 2nd edition has provided guidance on donation practice for the past 10 years and has been a source for national donation policy-making.

As the 10th anniversary of the 2nd edition approached, it was felt that a revision of the guidelines was needed in view of the changed landscape of medicine donation practices. A consultative process followed in 2009, including calls for comments via E-drug and ReliefWeb, and direct solicitation of comments from individual members of the Interagency Pharmaceutical Coordination (IPC) Group.[1] Comments received were categorized and discussed within a task force set up by WHO and a team of international consultants.[2] The process resulted in both adjustments to the existing text and addition of further content to cover donation practice in current international development assistance (Box 1).

1. The Interagency Pharmaceutical Coordination (IPC) Group consists of the senior pharmaceutical advisers of the World Health Organization, the World Bank, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Population Fund (UNFPA) and the United Nations Children's Fund (UNICEF). The IPC group meets every six months to coordinate the pharmaceutical policies underlying members' technical advice to partner countries and to plan and coordinate the preparation of interagency statements and technical documents.

2. Consultants for Health and Development bv, Leiden, the Netherlands.

Box 1. Changes in *Guidelines for medicine donations*, 3rd edition

Changes in this 3rd edition of the guidelines are based on a review of experiences and comments received through a consultative process. Key principles that were kept in mind when preparing the 3rd edition were:

- The guidelines should focus on protecting recipient countries from inappropriate donation practices.
- The guidelines should enhance the responsibility and involvement of recipients in the full process of medicine donations.
- The guidelines should emphasize the need for coordination in all phases of the donation process.
- The guidelines should put additional emphasis on the desirability of countries to develop a national medicine donations policy and to adopt national donation guidelines.
- The guidelines should provide guidance on appropriate donation practice for donors as well as for recipients.

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

Guidelines for medicine donations is based on four core principles that form the basis of good medicine donation practice, namely:

1. Donations of medicines should benefit the recipient to the maximum extent possible. All donations should be based on an expressed need. Unsolicited medicine donations are to be discouraged.
2. Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with the government policies and administrative arrangements of the recipient country.
3. There should be effective coordination and collaboration between the donor and the recipient, with all donations made according to a plan formulated by both parties.
4. There should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

This document contains a discussion of the need for guidelines, followed by the 12 guidelines for medicine donations. When necessary for specific situations, possible exceptions to the general guidelines are indicated. Chapter 4 describes the responsibilities of, and provides guidance to, both donor and recipient. It also suggests other ways in which donors may help and contains practical advice on how to implement a policy on medicine donations.

These guidelines are not an international regulatory document. They are intended to provide guidance that will achieve best donation practice by both donors and recipients, and to serve as a basis for preparing national or institutional donation guidelines. They are meant to be reviewed, adapted and implemented by governments and organizations dealing with medicine donations.

2. The need for guidelines

Medicines are an essential element in alleviating suffering. Thus, international development and relief efforts can benefit from appropriate donations. Medicine donations may take various forms, ranging from long-term donations of a single medicine for defined disease conditions to emergency donations of large varieties of medicines for general health-care delivery.

Appropriate medicine donation practice can have major advantages for both recipients and donors:

- A medicine donation can save lives and ease suffering when well coordinated and managed. In cases where recipient countries are not able to ensure adequate access to medicines, donations can bring major benefits to persons in need.
- Medicine donations can become a strategic benefit for the recipient country. Medicine donations are often used to support the rebuilding of health systems, or to ensure access of populations to health products they otherwise would not have.
- Good donation practices may provide savings in development support budgets, enabling these resources to be used for other purposes.

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. In addition, and as the examples below demonstrate, there are numerous examples of inappropriate medicine donations (see also Annex 1). Important problems encountered in the past include:

- Donated medicines were not relevant to the emergency situation, to the disease pattern or to the level of care that was targeted. Medicines have been provided that were unknown to local health professionals and patients, or that did not comply with locally agreed policies and standard treatment guidelines.

- Donated medicines have arrived unsorted and labelled in a language that was not well understood. Some donated medicines came under trade names that are not registered for use in the recipient country, and without an International Nonproprietary Name (INN) or generic name on the label. Sometimes medicines were donated without the required documentation.
- Medicines returned to pharmacies by patients, or free samples derived from health professionals, have been collected and donated to countries.
- Medicines have been donated in the wrong quantities, leading to situations where the large stocks could not possibly be used within their remaining shelf-life.
- Donated medicines with very short remaining shelf-life have been received in countries. In some cases they have expired before they reached the patients. Some stocks have had to be destroyed, sometimes at the cost of the recipient governments.
- Donor agencies have sometimes ignored local administrative procedures for receiving and distributing medical supplies. Distribution plans of the donor agencies have conflicted on occasion with the needs of national authorities.
- Some donors have donated medicines but recipients had no way to include these products in their inventory systems. The result has sometimes been that donations have piled up and expired as health systems had no way to account for them.

There are several reasons for these problems. Probably the most important factor is the common but mistaken belief that in low-income countries anything is useful – even health products that have no further use in other health systems. Another important factor is a lack of adequate communication between the donor and the recipient. This is unfortunate because in emergency situations inappropriate medicine donations may create extra work in sorting, storing and distributing donated supplies. Such additional work may easily overstretch limited human resources and transport capacity. Long-term donation programmes should keep in mind that not all medicines can be put to good use in the health-care systems of recipient countries.

Donating returned medicines (unused medicines returned to a pharmacy for safe disposal, or free samples given to health professionals) is an example of a double standard because in most countries their use would not be permitted owing to regulations on quality control. Such donations also frustrate management efforts to administer medicine stocks in a rational way. Prescribers are confronted with many different medicines and brands in ever-changing dosages, while patients on long-term treatment suffer because the same medicine may not be available in future. For these reasons this type of donation is forbidden in an increasing number of countries and is discouraged elsewhere.

An often forgotten aspect of donated medicines is that they may have high declared values (i.e. the market value in the donor country rather than the world market price). This may result in high import taxes and overhead costs for storage and distribution. In some cases the (inflated) declared value of a donation has been deducted from government medicine budgets. Sometimes the total handling costs (duties, storage, transport) are higher than the actual value of the medicines. Additionally, stockpiling of unused medicines may encourage pilfering and black market sales.

The negative impact that donations may have on sustainable access to medicines is often not well appreciated, especially where it concerns expensive medicines with few alternatives. Donations of these products may influence the market and suppress competition. The donation may eliminate or greatly delay the import of cheaper alternatives, which will be necessary once the donation programme has ended and regular provision from public health budgets is necessary.

Clear guidelines that are endorsed by the major international donors and development agencies can be helpful. In summary:

Donors and international development agencies generally are well-intended, but do not always realize the possible inconveniences and unwanted consequences in recipient countries.

The need for medicines – both to ensure adequate health-care delivery and to manage emergency situations – may vary between countries and from situation to situation. The selection of medicines to be donated must be based on a sound analysis of needs. Their quantification must be done in close cooperation with recipients, and distribution must fit with existing policies and administrative systems. Unsolicited and unnecessary medicine donations are wasteful and should not occur.

The quality requirements of medicines are different from those of other donated items such as food and clothing. Medicines can be harmful if used inappropriately. They need to be easily identifiable through clear and understandable labels and written information. As they may expire, there must be a professional means of destroying them.

- Long-term donations also include medicines that are required for lifelong treatment. Unexpected discontinuation of these medicines can have severe results as the disease may become recurrent. Also, resistance to the medicine may develop. At the start of a long-term donation programme, a plan should be prepared on how to phase out a donation and how to review the donation.

As a general rule, medicine donations are neither a long-term solution to underfunded health systems nor a solution to the lack of access to medicines in poor countries – especially for diseases that require lifelong treatment or large numbers of treatments. However, donations can be temporary solutions to defined problems.

Sometimes donations may achieve the contrary to what was intended. For instance, recipient countries may consider it advantageous to receive medicines for free, without giving sufficient consideration to known side-effects of medicine donations – such as reliance on external donations that hamper the development of low-cost generic equivalents, or the additional human resources that are needed to manage the donations. However, well designed and well managed donation programmes may have significant benefits for both donors and recipients and may lead to positive collaboration between both partners.

3. Guidelines for medicine donations

3.1 Selection of medicines

1. All medicine donations should be based on an expressed need, should be relevant to the disease pattern in the recipient country, and quantities should be agreed between donor and recipient.

Justification and explanation

The prime responsibility for specifying needs is with the recipient. 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.

Possible exceptions

In acute emergencies, the need for prior consent by the recipient may be waived, provided that the medicines are among those on the WHO model lists of essential medicines[1,2] or are included in the United Nations list of emergency relief items recommended for use in acute emergencies.[3]

2. All donated medicines or their generic equivalents should be approved for use in the recipient country and should appear on the national list of essential medicines or equivalent or in the national standard treatment guidelines, if the NEML is not updated. Or, if a national list is not available, it should appear on the WHO model lists of essential medicines, unless specifically requested otherwise and provided with a justification by the recipient.

Justification and explanation

Medicine donations must comply with national medicine policies, essential medicines programmes, and national treatment protocols.

Possible exceptions

An exception can be made for medicines needed in sudden outbreaks of uncommon or newly emerging diseases. Not all medicines appropriate for those conditions are also approved for use in the recipient country in question. In such cases, donors should duly inform recipients of the regulatory status of products to be donated, and should obtain agreement.

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

Justification and explanation

Staff at the different levels of health care in recipient countries have often been trained to use 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

4. All donated medicines should be obtained from a quality-ensured source and should comply with quality standards in both donor and recipient countries. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce[4] should be used.

Justification and explanation

Double standards should be prevented: 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 should be manufactured in accordance with international standards of good manufacturing practices (GMP).

Possible exceptions

In acute emergencies, where pre-stock or the emergency health kit are not in place, the use of the WHO Certification Scheme may not be practical. However, if it is not used, a solid justification should be given by the donor. When donors provide funds to purchase medicines from local producers, those which comply with national standards should not be excluded solely on the grounds that they do not meet the quality standards of the donor country. Strict criteria should be adhered to. See UNHCR's drug management manual.[1]

5. No medicines should be donated 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.

Justification and explanation

Patients return unused medicines to a pharmacy to ensure their safe disposal. In most countries it is not permitted to issue returned medicines to other patients 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 workers should not be further distributed as donations to other health systems.

1. UNHCR. Drug manual for local transport, 2006, 33. Available at: http://www.unhcr.org/43cf66132.html.

6. After arrival in the recipient country 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.

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 store, provincial store, district hospital) may take a number of months. Donation of medicines just before their expiry should be avoided as in most cases they will reach patients after expiry. The argument that short-dated products can be donated in the case of acute emergencies, because of their immediate use, is incorrect. In emergency situations the systems for receipt, storage and distribution of medicines are often disrupted and overloaded, and donated medicines tend to accumulate.

Possible exceptions

An exception may be made for direct donations to specific health facilities, provided that (i) professional staff at the recipient institution are aware of the limited shelf-life and (ii) the quantity and remaining shelf-life allow for use prior to expiry. A second 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, with a minimum of six months. The national donation policy may specify the minimum acceptable remaining shelf-life for donated medicines.

3.2 Presentation, packaging and labelling

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

Justification and explanation

Health systems generally operate 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. In the case of injections, the route of administration should be indicated.

8. Donated medicines should be presented in pack sizes that are suitable for the recipient and appropriate to the setting in which they will be distributed or dispensed.

Justification and explanation

Large quantity packs tend to be more appropriate for public sector supply systems in most recipient countries. They are less bulky and allow for quick and effective distribution and dispensing to patients. When possible, liquid formulations (syrups and mixtures) should be avoided because of their more demanding logistical needs. Where relevant, medicines for use in children should be listed in the WHO Model List of Essential Medicines for Children.

9. 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. The weight per carton should preferably not exceed 30 kilograms. Shipments of medicines should not be mixed with other supplies, unless they are shipped as kits with predetermined contents.[1]

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

10. Medicine donations should be jointly planned, and collaboration between donors and recipients should begin early. Medicines should not be sent without prior consent of the recipient.

Justification and explanation

Adequate coordination is needed between health "clusters" of the international response system in order to avoid gaps in assistance and duplication of efforts during emergencies. 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. Pharmacists should be involved, either directly or by advising others, in the arrangements for donations of medicines [2]

1. For information on the New Health Emergency Kit, see Section IV.I.4.2.

2. FIP Statement of Policy on Good Practice in Donations of Medicines, 1997. Available online: http://www.fip.org/www/uploads/database_file.php?id=196&table_id=

11. In the recipient country the declared value of a medicine donation should be based on 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 medicine donations from being valued in the recipient country according to the retail price of the product in the donor country – which can 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 medicine 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.

12. 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 recipient 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.

4. Guidance to donors and recipients

This section aims to help both donors and recipients to optimize the benefits of medicine donations. Starting with a discussion on shared responsibilities, Section 4.2 provides specific guidance for donors of medicines, including suggestions on other ways donors may help. Section 4.3 provides specific guidance for recipients, including practical information on how to implement a medicine donation policy.

4.1 Collaboration, roles and responsibilities

When a donation of medicines is being considered, careful planning is very important, independent of whether it concerns a long-term donation of a single medicine for a defined disease condition or an emergency donation of a large variety of medicines for general health-care delivery. Coordination and harmonization between the donor and the recipient is essential.[5] Mutual respect is of fundamental value in achieving effective donations, and recipients should be able to reject a donation when they feel it is not in the best interests of their country or institution.

In emergencies, from the early stages of planning donation, there should be strong collaboration with relevant national and international NGO networks and with WHO health clusters. (See Box 1). Utilization of the communication networks and mechanisms already in place is very important, as is sharing of information on needs and responses. To optimize collaboration, a coordinating mechanism for medicine donations is recommended. This

mechanism should determine needs, priorities and quantities required. The coordinating mechanism can act as the central point of contact, is responsible for the dissemination of information and should ensure that the donation complies with the national donation policy. This principle should be adhered to for donations in emergencies as well as in non-emergency situations. At headquarters level, donors are recommended to set up coordinating mechanisms to ensure that appropriate donation policies and processes are followed.

Box 2. The World Health Organization WHO Global Health Cluster

The Global Health Cluster (GHC) is an initiative led by WHO. The cluster is made up of more than 35 international humanitarian health organizations and agencies that have been working together over the past four years to improve the predictability and accountability of humanitarian health action. The GHC aims to develop common approaches in order to optimize health outcomes through timely, effective, complementary and coordinated action before, during and after crises.

The work of the GHC is based on four strategic priorities which provide a structure for examining accomplishments and challenges. The priorities are to:

- build capacities within country health clusters to design, implement and monitor an effective and evidence-based humanitarian health response;
- ensure that supplementary human and material resources are readily accessible to country health clusters;
- specify humanitarian health priorities and coordinate global actions to address them;
- monitor and evaluate the progress and effectiveness of the health cluster at global and country levels over time.

The GHC aims to improve information-sharing among partners on existing global and regional stockpiles of emergency medical supplies and pharmaceuticals. It also explores possible stockpile coordinating and tracking tools for promotion and training at country level. In addition, the GHC promotes related best practices, including *Guidelines for medicine donations*, among partners and the donor community at country and global levels.

See: http://www.who.int/hac/global_health_cluster/about/en/index.html

Roles and responsibilities in all phases of the donation should be established *before* the donated medicines arrive in the recipient country. Responsibilities for transport, customs clearance, reception, storage and distribution, administration, monitoring and evaluation and – where warranted – disposal of donated medicines should be agreed in writing and signed by the donors and the recipient. Donors and recipients should be able to demonstrate that each party has the right capacity to carry out these tasks effectively. Where capacity is weak, efforts should be made to increase capacity before a donation is shipped.

Recipient governments have the responsibility to supply donors with information about requested and approved donations. Conversely, donors should keep recipients informed in detail of the contents of planned donations as well as the arrival information. This information is important for the proper reception of the shipments and for further distribution of the medicines.

Monitoring and evaluation

Evaluation of the appropriateness of medicine donations is an absolute necessity that determines the effectiveness, efficiency and adequacy of current and future donations. Monitoring and evaluation data may help to prevent the continuation or repetition of inefficient or harmful donations, modify inappropriate donation programmes, adjust forecasting and improve management. Evaluations should include assessments of the administrative process used by the donor agency, the adequacy of selection and forecasting, appropriateness of the medicines, timeliness of delivery and changes in treatment guidelines. Health cluster partners should collectively monitor the implementation of the overall health crisis response strategy and should ensure that the overall health cluster/sector response is evaluated (Box 2). A cost–benefit analysis may help in determining the donation's usefulness to the donor and the recipient. Long-term donation programmes should be evaluated periodically. In emergencies, the appropriateness of the medicines should be monitored and evaluated as part of the evaluation of the disaster response. The disaster response team will be the most appropriate to handle this.

Phasing out

Long-term donations may include medicines for lifelong use. Unplanned termination of these treatments may have serious effects so a carefully planned phase-out is necessary. In most cases this would be a plan of how government funding would take over procurement and management of these medicines, including realistic estimates of the procurement costs involved and development of a scenario on how to budget for those costs.

4.2 Guidance to donors

In addition to shared responsibilities for both donors and recipients, donors should be aware of a number of specific issues within their influence.

Needs of the recipient should guide the donation

In the past, medicines have been donated in wrong selections and quantities, leading to situations in which stocks could not possibly be used within their remaining shelf-life and therefore required costly and inconvenient destruction procedures. Donations should be planned on the basis of the needs of the recipient country. Competition between donors is unhelpful, and attempts to satisfy the most visible needs of the recipient may not be the best help that a country needs. The quality and appropriateness of the donation is more important than its size or monetary value. Despite tragic images shown in the media, it is necessary to work with general assessments of the needs, to wait for the country's requests for aid, to maintain contact with organizations in the field, and to rely on relevant and adequate information before planning a medicine donation. On some occasions donations have been earmarked by the donor for specific activities or programmes. Whereas

earmarking is understandable from the donor's point of view, recipients should be allowed to apply flexible criteria when establishing priorities and meeting the changing needs of the population.

Administrative arrangements should not be ignored

Donors should respect the laws, regulations and administrative procedures of the recipient country in all instances. Donated medicines should be treated as if they were procured. They should be included in the National Essential Medicines List (NEML). Shipments should be accompanied by documents to prove compliance with quality standards, including the INN or generic name, batch number, dosage form, strength, name and country of the manufacturer, quantities in the container, storage conditions and expiry dates. This enables the recipient to trace back the product in case of suspicion about the quality. Donors should consult the relevant Ministry of the recipient country for special documentation requirements in order to ensure smooth reception and clearance. Where appropriate and whenever possible, donated medicines should have clearly labelled indications and counter-indications for pregnant and lactating women, for children (i.e. paediatric labelling), and for persons suffering from other health conditions (e.g. high blood pressure). Specific markers to prevent misuse and pilferage may be considered. To simplify the registration process of the donation, donors should ensure that the information is easy to register.

The public in donor countries should be informed

Populations in donor countries are not always aware of the possible problems of medicine donations. Guidelines on the donation practices of the donor country should be in the public domain. It is important for governments in donor countries to create public awareness of "good donation practice". The best moment for this is probably when the public appeal is announced in the media. In some cases an important message may be that donations of goods other than medicines, or even cash resources, may have preference.

The recipient must have adequate capacity to handle the donation

Donated medicines should be entered into an inventory system, distributed through existing distribution channels and be subject to quality assurance procedures. Donors should ensure that the recipient's capacity to manage the donation is sufficient and that logistical disasters are prevented. This includes the capacity to store (including a functional cold chain) and distribute, and functioning administrative systems. Donation planning should not start before a responsible party has been identified or before adequate capacity to carry out these functions is in place.

Remaining shelf-life of donated products should be discussed

Donations of medicines with short remaining shelf-life have caused trouble for recipients for many years. Donors and intermediaries should prevent such poor practices. Interaction with recipients is of key importance in determining the acceptability of the remaining shelf-life of products being considered for donation. Global experience indicates that well-managed donor organizations and private sector suppliers are able to avoid donating products with too little remaining shelf-life.

Management of expired products must be agreed in advance

Appropriate disposal or reverse logistics of expired products must be agreed in advance. In principle the donor should accept responsibility for the destruction or withdrawal of donated medicines when necessary. Where national laws or guidance are insufficient, WHO's *Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies* should be followed for destruction of expired medicines.[6] Donors should ensure that a system is in place for collecting and processing complaints about donated products.

Other ways donors can help

The interagency emergency health kit

In the acute phase of an emergency, such as internal displacement or where refugee populations cross the border, it is often best to supply standardized kits of medicines and medical supplies that are specifically designed for this purpose. The interagency emergency health kit,[7] which has been widely used during the past two decades and the contents of which have been twice updated, contains medicines, disposable supplies and basic equipment needed for the general medical care of a population of 10 000 for three months. The kit is permanently stocked by several major international suppliers (e.g. the International Dispensary Association, Médecins Sans Frontières, UNICEF) and can be made available within 48 hours. It is especially relevant when recipients cannot quickly prepare well defined requests.

Donations in cash

Donations in cash for regular supplies of essential medicines are sometimes more welcome than (further) medicine donations in kind. Cash contributions can support the activities of the local government or coordinating committee and local and regional industries. They may also be more cost-effective. With cash donations, governments may be able to procure health products that prescribers and patients are familiar with, as opposed to those that international agencies are able to supply. In emergencies, donors need to look out for appeals indicating priority areas of need for funding.

4.3 Guidance to recipients

In addition to shared responsibilities for donors and recipients and specific guidance to donors, recipients should be aware of a number of specific issues within their influence. These include defining needs and quantities, as well as planning and coordinating reception, storage and distribution. Recipient countries should have defined procedures for valuation, for entering donations in their budget records, and for the disposal of inappropriate donations.

Define national guidelines for medicine donations

To be prepared for a situation in which donations of medicine are useful or needed, countries should formulate their own national donation policy and guidelines for medicine donations. National guidelines should preferably be formulated on the basis of international guidelines. In the national policy and accompanying guidelines, recipients should explain what kind of assistance – including medicine donations – they need, what minimum requirements medicine donations should meet, and what is not welcome. The national policy and guidelines should be officially presented and explained to the donor community and should be publicly accessible. Where applicable, they may be part of an emergency preparedness plan. The national medicine donation guidelines should include information on how emergency responses are coordinated, including how medicine donations are coordinated in cases of emergency.

Needs for donated medicines should be well specified

The recipient is responsible for specifying the needs when a medicine donation is being considered. Recipients should carefully and precisely prepare requests, indicate the required quantities and prioritize items. In addition, it is recommended to specify the appropriate language of use on products and special medications for children. To avoid duplication, recipients should provide potential donors with information on donations that are anticipated or are already in progress.

Minimum remaining shelf-life must be defined by the recipient

Recipients should be clear as to the minimum remaining shelf-life that is appropriate to the national policy on medicine donations. To avoid unnecessary impounding and disposal of valuable donations, recipient governments should consider possible exceptions to their general rules on remaining shelf-life.

Rapid customs clearance of donated medicines is important

Rapid customs clearance is required for all donated medicines. Customs and health ministry officials managing medicine donations have the responsibility to allow entry of useful donations and to reject unsuitable donations. The criteria for acceptance and rejection of donations should be published in the national donation guidelines and should be communicated to donors.

Incoming donations must be registered

Data on goods entering the country, who donated them and where they will go, should be registered from the start of any donation effort. Even in emergency situations, when aid arrives quickly and is sometimes uncoordinated, a central registry of all donations continues to be important. Such registries facilitate the management and organization of donations and promote transparency and responsibility. Registries should be developed on the basis of the national donation policy. Where possible, electronic systems should be implemented to simplify registration. To avoid duplication of effort or of resources, cash donations from multilateral agencies and specialized NGOs should also be registered. In cases where donors monitor their donations themselves, access to this information will allow the recipient to set

up the management systems required for the assistance received. Inventory control information should be provided in electronic format to simplify the task.

Adequate handling of donations at arrival

The value of donated medicines may be considerable, and the gift should be treated with due efficiency and care. On arrival the medicines should be inspected and their receipt confirmed to the donor agency. They should be stored and distributed in accordance with the 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 or commercial sale, or into illicit channels. Good donation management also includes agreed systems of accountability.

Annex 1. Examples of problems with medicine donations

Gujarat, India, Earthquake, 2001

Drug donations following the earthquake met most of the guidelines related to selection of drugs, quality assurance and shelf life, presentation, packaging and labelling, and information management. Prior to the earthquake, this region of India had an established disaster management system to receive medical assistance. This included an essential drugs list and a defined central to peripheral organization scheme for handling medicine donations. There was also a local buffer supply of essential medicines that was available for immediate aid. After the earthquake, medical needs were assessed and there was a public request for appropriate medicines through the media. This served as a guideline for drug distribution in the area and for donors. A large number of medical personnel were deployed to handle donations. Of the 1,308 tons of drugs donated, 95% were appropriate. In general, the medicines were clearly labelled and had expiry dates that were at least one year from the time of arrival in India. The aid workers were familiar with most of the drugs, as a majority came from India. Although the majority of drug donations were in compliance with the WHO Drug Donation Guidelines, the amount donated far exceeded the need, resulting in costs to the recipient country from drug destruction.[8]

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 NGOs, 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 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.[9]

Long-term donation -- managing 'in-kind US$ drug donations'

In the United Republic of Tanzania, a 30% gap in supply of medicines has been identified and this gap is met by drug donations. An evaluation of the use of drug donations identified several issues. Donations of medicines were frequently not provided over a sufficient length of time, and medicines provided did not meet the needs of the country's essential medicines programme. There was a need to ensure that donated medicines met the country's regulatory requirements although there were mixed views about exactly what quality standards should be applied. Other issues identified were lack of transparency in the processes of receiving donated medicines, poor or no communication between the donor and the recipient, and inadequate infrastructure to use the donations effectively. Overall, the authors of the evaluation concluded that there was a need to implement the national medicine donation guideline effectively, and for better communication between donors and recipients, and transparency and accountability in respect of donations received.[10]

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

The guidelines are intended to provide guidance that will achieve best donation practice by both donors and recipients, and to serve as a basis for preparing national or institutional donation guidelines. They are meant to be reviewed, adapted and implemented by governments and organizations dealing with medicine donations.

Changes in this 3rd edition of the guidelines are based on a review of experiences and comments received through a consultative process. Key principles that were kept in mind when preparing the 3rd edition were:

- The guidelines should focus on protecting recipient countries from inappropriate donation practices.
- The guidelines should enhance the responsibility and involvement of recipients in the full process of medicine donations.
- The guidelines should emphasize the need for coordination in all phases of the donation process.
- The guidelines should put additional emphasis on the desirability of countries to develop a national medicine donations policy and to adopt national donation guidelines.
- The guidelines should provide guidance on appropriate donation practice for donors as well as for recipients.

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International Health Partners

PQMD
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