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## CHAPTER 15

# Pharmaceutical donations

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## SUMMARY

Most pharmaceutical donations are given with the best of intentions but can nevertheless create problems at the receiving end. Often, donated pharmaceuticals are not relevant to the needs of the recipient, or they arrive unsorted or close to expiry. They may be labeled with a brand name or in a language that is not understood. Many pharmaceutical donations counteract government policies or violate national regulations of the recipient country and can be expensive for the country to store or destroy.

Guidelines for pharmaceutical donations are needed for a number of reasons. Donors and recipients do not communicate on equal terms, and recipients often need assistance in formulating their needs. Many donors do not understand the potential difficulties at the receiving end and need guidance. Medicines require special regulations because they are different from other donated items. Pharmaceutical donations that occur without input from the recipient countries should be discouraged.

The four core principles for a useful pharmaceutical donation are—

1. A donation benefits the recipient to the maximum extent possible.
2. A donation should be given with full respect for the wishes and authority of the recipient.
3. Items that are not acceptable in the donor country for quality-related reasons are also not acceptable as donations: there should be no double standards in quality.
4. Effective communication between the donor and recipient is necessary before any donation.

These principles have been translated into a set of guidelines for pharmaceutical donations. First, recipients should review and adopt these guidelines and present them officially to the donor community. Only then can they be implemented and enforced. Second, recipients should develop and publish administrative procedures for pharmaceutical donations. Third, recipients should indicate to the donors, as clearly as possible, how they want to be helped, specifying the medicines they need, the quantities, and the priorities. Donors should inform the recipients well in advance which pharmaceutical donations are coming, and when.

### 15.1 Introduction

In the face of disaster the natural impulse is to reach out and help those in need. Donations of medicines can alleviate peoples' suffering, and international relief efforts benefit enormously from donations by private individuals, groups, and organizations. Organizations may donate pharmaceuticals or medical supplies for a variety of reasons. Some may seek tax deductions that can result from charitable donations; some may be seeking positive publicity; while others may want to dispose of unwanted products without having to pay for destruction. Unfortunately, many pharmaceutical donations have caused problems instead of helping.

This chapter summarizes the problems with inappropriate pharmaceutical donations, describes a set of guidelines for donations, and offers some practical recommendations for recipients and donors.

### 15.2 Problems with pharmaceutical donations

Many different types of pharmaceutical donations exist, and each has its own set of specific problems. The types covered in this section are—

- Pharmaceutical donations in emergency situations

- Pharmaceutical donations between governments as part of development aid
- Donations of returned or unwanted pharmaceuticals

#### Pharmaceutical donations in emergency situations

A sizable disaster does not always lead to an objective assessment of the emergency medical needs, based on hard facts and past experience. Frequently, an emotional appeal for massive medical assistance is issued. In times of emergency, the term “medical supplies” has special emotional connotations that can impede an objective approach. Although Country Study 15-1 provides examples of targeted emergency donations guided by quickly published lists of needs (e.g., in Haiti and Lebanon), more often than not, emergency pharmaceutical donations are inappropriate, which is why donors are often urged to respond to a disaster with cash rather than products (Pinheiro 2008). The main problems can be summarized as follows—

- Donated pharmaceuticals are often not relevant for the emergency situation, for the disease pattern, or for the level of care that is available.
- Health workers and patients are not always familiar with the donated pharmaceuticals.
- The pharmaceuticals are often not registered for use in

the recipient country and may not comply with local treatment guidelines.

- The pharmaceuticals that arrive are frequently unsorted, difficult to identify, unknown in the recipient country, labeled with brand names, or labeled in a language that is not locally understood.
- The quality of the pharmaceuticals does not always comply with standards in the donor country. Donated pharmaceuticals may have expired or may expire before they reach the patient; they may be returned pharmaceuticals (half-finished packages that have been returned to the pharmacy or free samples given to health professionals) (see Ette 2004); or they may be unwanted by the donor because they are close to expiration or the product is being discontinued (donating such products is also known as *drug dumping*). Donations may spoil or become damaged, which may be impossible to detect in the recipient country.
- The distribution plan often ignores normal administrative procedures. For example, the distribution system may bypass the central government stores or otherwise conflict with the plan of the national authorities.
- Donated pharmaceuticals may have a high declared value reflective of the market value in the donor country rather than the world market price. This valuation may result in high import taxes and overheads for storage and distribution in the recipient country, and the inflated value of the donation may be deducted from the recipient government's pharmaceutical budget.
- Pharmaceuticals may be donated in the wrong quantities or be otherwise unusable, and some stocks may have to be destroyed. Disposing of pharmaceuticals is not only wasteful; it is expensive for the recipient to safely destroy pharmaceutical stock.

There are several underlying causes for these problems. The most prominent cause is probably the common but mistaken belief that any type of pharmaceutical is better than nothing at all or, similarly, that expired pharmaceuticals are good enough for people in need. Second, pharmaceutical donations are often made despite the lack of a stated need or prior clearance by the recipient. Third, in many donor countries, donated pharmaceuticals are tax-deductible (at full market price). This last factor is why so many donated pharmaceuticals arrive close to or past their expiry date and why such products are typically not high-use, high-volume items. Pharmaceutical donations initiated by pharmaceutical manufacturers in exchange for tax breaks are likely to consist of medicines and supplies that are not commonly viewed as essential.

Inappropriate pharmaceutical donations create logistical problems because the donated products must be sorted, stored, and distributed, sometimes using precious human

resources and transport volume in disaster areas or war zones. Or they may pose an environmental threat if they have to be destroyed. Often, the total transport costs are higher than the value of the pharmaceuticals. Stockpiling of unused pharmaceuticals can encourage pilfering and black-market sales.

Even donations that are appropriate in every other way can cause problems when they far surpass the quantities that are needed. For example, a World Bank analysis of pharmaceutical donations during emergencies indicated that in Gujarat, India, after an earthquake in 2001, 95 percent of the donations received were deemed appropriate, but exceeded what was needed by 1,178 tons (Autier et al. 2002).

### Pharmaceutical donations as part of development aid

Most of the problems noted above may also apply to large pharmaceutical donations between governments given as part of development (commodity) aid. The situation is usually better than with emergency aid, however, as there is more time to plan for the donations. Generally, the recipient is more involved in specifying what is needed.

The ideal situation occurs when the recipient country can indicate specific medicines and quantities needed, without any restriction on the selection and country of origin of the pharmaceuticals. Unfortunately, these conditions seldom apply. The choice is often restricted to manufacturers or suppliers in the donor country. Even if the medicines are listed generically on the national list of essential medicines in the recipient country, the donated items are often brand-name products or different formulations that may not be registered in the recipient country. The donation may then interfere with the implementation of national registration, quality assurance, and inspection schemes. If the selection of medicines is restricted by the donor, the donation may not be in accordance with national programs promoting standard treatment guidelines and rational medicine use.

### Donations of returned pharmaceuticals

Many nongovernmental groups in developed countries collect unused medicines (returned medicines or free samples) and send these products in emergency situations or, on a regular basis, to institutions in developing countries. At the receiving end, such donations can frustrate all efforts to manage and administer pharmaceutical stocks in a rational way. Donating returned medicines is a clear example of double standards: in no developed country would the use of such products be permitted. In addition, these medicines are a problem for doctor and patient. The prescriber is forced to use countless different medicines and brands in ever-changing dosages; patients on long-term treatment suffer because the same medicines may not be consistently available. For

### Country Study 15-1 Multicountry experiences with pharmaceutical donations

**Bosnia and Herzegovina, 1997.** During the war in Bosnia and Herzegovina, many areas became dependent on foreign donations of medicines and medical supplies. An estimated 27,800 to 34,800 metric tons of medical materials were brought into the area between 1992 and mid-1996. Three types of donations were identified, each inappropriate to some degree. The first type of donation conformed to WHO's interagency guidelines for pharmaceutical donations, but approximately 5 percent of the 13,200 metric tons of this donation were considered inappropriate, because it consisted of prepackaged kits that were not fully applicable to local health needs. The second type of donation consisted of small amounts of miscellaneous medicines that were largely delivered unsorted, unidentifiable, or expired, and were frequently items not useful for the local health problems. The third type of donation comprised large quantities of useless or unusable medicines—what is known as drug dumping. In total, 50 to 60 percent of all the medical supplies donated to Bosnia and Herzegovina were deemed inappropriate (Berckmans and Autier 1997).

**Croatia, 1991.** Starting in 1991, war and political instability affected countries that were part of the former Yugoslavia, prompting large amounts of pharmaceutical donations from the international community. In Croatia, 2,700 tons of inappropriate donations of foreign origin classified as “pharmaceutical wastes” were stored in 250 warehouses. USD 4 million was budgeted to ensure its safe disposal (World Bank 1999; Stritof and Vrhovac 1997, cited in Autier et al. 2002).

**East Timor, 1999.** When East Timor declared independence from Indonesian rule, a militia-led campaign of destruction ensued. Seventy-five percent of the population of 850,000 was displaced, and almost 70 percent of the country's infrastructure was destroyed. Assessments estimated that inappropriate donations to East Timor comprised about 10 percent (by volume) of the total donations received during the emergency phase, and less than 5 percent of donations after March 2000. Although the pharmaceutical donations in East Timor had some problems, several reasons why the donations were generally acceptable included—

- Direct connections by air or water to the island are difficult, so supplies went through Australia, which facilitated surveillance.
- The United Nations coordinated significant donations, which came in the form of New Emergency Health Kits, which helped limit ad hoc donations.

- Media coverage was scant.
- Pharmaceutical companies were willing to make donations that complied with WHO's donation guidelines.

The East Timor experience suggests that the WHO donation guidelines can positively affect pharmaceutical donations in emergency and postemergency situations (Autier et al. 2002).

**El Salvador, 2001.** Two earthquakes hit El Salvador in 2001, affecting at least 25 percent of the total population and up to 75 percent of the population in specific areas. Immediately following the disasters, pharmaceutical donations began to arrive in the country. Although a government-led coordination body managed the donations, the effectiveness of the system was diminished because of a lack of coordination with the agencies sending out the medicines, and lack of classification skills within the country for medicine sorting. Total pharmaceutical donations approximated 882 tons. Approximately 37 percent of the total volume of donated medicines was defined as inappropriate, and an additional 12.9 percent was defined as “mixed unusable drugs giving rise to suspicion of dumping” (Autier et al. 2002).

**Eritrea, 1993.** During the war for independence, despite careful wording of appeals, much time and energy had to be spent sorting pharmaceutical consignments. Examples of inappropriate donations included seven truckloads of expired aspirin tablets that took six months to burn, a whole container of unsolicited cardiovascular-related medicines with two months to expiry, and 30,000 half-liter bottles of expired amino-acid infusion that could not be disposed of anywhere near a settlement because of the smell.

**Gujarat State (India), 2001.** A major earthquake occurred in the state of Gujarat in 2001 in an area that was already experiencing a severe drought. India has an established natural disaster management system with a defined chain of command from the central to peripheral level. Officers were stationed at checkpoints to facilitate arrival and movement of supplies and donated goods, and the government had a coordination committee to synchronize the activities of various donors. The result was that the majority of pharmaceutical donations to the area appeared to be appropriate and clearly labeled, and had expiry dates that were at least one year from the time of arrival in India (Autier et al. 2002).

**Haiti, 2010.** A 7.0 earthquake struck Haiti on January 12, 2010. From January 16–21 alone, approximately 530 tons of pharmaceutical supplies arrived at the Port-au-Prince airport (PAHO/WHO 2010b), and another 810 tons of medical supplies were donated before February 6 (PAHO/WHO 2010a). PROMESS (the Program on Essential Medicine and Supplies), Haiti’s central pharmaceutical store, was responsible for organizing the donations. With the assistance of the Pan American Health Organization and the U.S. government, PROMESS staff worked with medical personnel to help receive, sort, and check the expiration dates of the pharmaceutical donations, so that the items could be shelved. They also dealt with the challenges of providing security for the donations and the PROMESS facility. The Ministry of Public Health and Population waived any fees for essential medicines until four months after the disaster to assure maximum access to medicines.

**Lebanon, 2006.** During a Middle East humanitarian crisis, more than a quarter of the Lebanese population was displaced, and 50 to 70 percent of health facilities were partially or completely destroyed in the affected border regions. In addition, the supply of fuel, medicines, and medical supplies was disrupted. WHO posted a list of needed medicines and supplies—mostly for chronic diseases and surgical interventions—to guide donations. The local WHO coordinator said, “Lebanon needs medicines, but it needs the right kind. Every box of medicines or other supplies donated has to be checked, sorted, stored, and shipped to the right places.” Reports indicated that most of the donations that came in were exactly what the country needed (WHO 2006b).

**Lithuania, 1993.** Eleven women in Lithuania temporarily lost their eyesight after using a medicine that had been provided through pharmaceutical donations. The medicine, closantel, was an anthelmintic that should be used only in veterinary medicine but was mistakenly given for the treatment of endometritis. The donation had been received without product information or package inserts,

and doctors had tried to identify the product by matching the name on the box with the names on leaflets of other products.

**Mozambique, 2000.** In 2000, Mozambique was hit by the worst floods ever recorded in the country, resulting in 700 deaths and displacing more than 500,000 people. As news of the disaster spread, a huge volume of aid cargo was sent, but delivery was chaotic. One person involved reported that “[a]t least 71 shipments arrived during 45 days, most without warning, many with no documentation or packing list” (Christie and Hanlon 2001). Overall, the international community donated 514 tons of medicines, but only 130 tons, or 25 percent, corresponded to requests issued by the ministry of health; three-quarters were considered inappropriate (Autier et al. 2002).

**Rwanda, 1994.** At the peak of the refugee crisis, a large international pharmaceutical company donated six million units of Ceclor CD, a sophisticated antibiotic. The refugee workers had no experience with this medicine, so it was not used. Part of this donation was returned to the donor, and the remainder expired and had to be destroyed (Purvis 1996 in Autier et al. 2002).

**Sudan, 1990.** A large consignment of pharmaceuticals was sent from France to war-devastated southern Sudan. Each box contained a collection of small packets of medications, some partly used. All were labeled in French, a language not spoken in Sudan. Most were inappropriate; some could be dangerous. Items included contact lens solution, appetite stimulants, monoamine oxidase inhibitors (dangerous in Sudan), X-ray solutions, drugs against hypercholesterolemia, and expired antibiotics. Of fifty boxes, twelve contained products that could be of use. It would have been much better to have used the money spent on transport to purchase penicillin and other essential medicines in Kenya, which could then have been sent to Sudan.

Source: WHO/DAP 1999 unless otherwise noted.

these reasons, this type of donation is generally discouraged and even forbidden in some countries. The immense effort required to sort such donations is largely wasted because most of the products are unusable.

### Disposal of unwanted pharmaceuticals

The best way to avoid having to dispose of unwanted pharmaceutical donations is to stop inappropriate donations from occurring; unfortunately, however, even with

increased recognition of problematic donations in the face of large-scale disasters, such as the 2004 South Asian tsunami, disposal remains an important issue. The same international coalition that developed the WHO Drug Donation Guidelines has collaborated on guidelines for the safe disposal of pharmaceuticals. These guidelines were based on experiences during the war in Bosnia and Herzegovina, where an estimated 1,000 to 17,000 metric tons of unused medicines were stockpiled, requiring disposal at a quoted cost of USD 2.20–4.10 per kilogram (WHO 1999). There

have been calls for donors to take responsibility for paying for disposal of unused donations (Ciment 1999).

### The need for guidelines

The examples of inappropriate donations discussed above illustrate the need for international guidelines for pharmaceutical donations. In summary, guidelines are needed because—

- Donor and recipient do not communicate on equal terms; recipients, therefore, need assistance in specifying how they want to be helped.
- Many donors mean well but do not realize the difficulties at the receiving end and need guidance.
- Pharmaceutical needs vary by country and situation. Donations should be based on an analysis of actual needs, and selection and distribution must fit within pharmaceutical policies and administrative systems. Inappropriate donations frustrate the implementation of national pharmaceutical policies and programs to promote rational medicine use.
- Medicines are different from other donated items. Medicines can be harmful, they require labels and written information, they need special storage conditions and adequately trained personnel to be used effectively, they may expire, and they may have to be destroyed in a particular way.

### 15.3 Chronology of existing guidelines for pharmaceutical donations

In 1988, the Christian Medical Commission (CMC) of the World Council of Churches in Geneva was the first organization to issue guidelines for pharmaceutical donations. This carefully worded document was specifically intended to make more rational the many donations that are made to individual church-related hospitals by well-intentioned but ignorant groups or individuals.

In 1990, the WHO Action Programme on Essential Drugs, in collaboration with major international emergency aid agencies, issued a set of guidelines for donors that was included in *The New Emergency Health Kit*, which was updated in 1998, and again in 2006 (WHO 2006a). As with those of the CMC, these guidelines stress that donations should be based on a specific request by the recipient and should, in all cases, be cleared before dispatch. Minimum labeling and outside packaging information standards are also specified.

In 1994, the WHO office in Zagreb issued detailed guidelines for humanitarian assistance for the former Yugoslavia, where WHO acts as a clearinghouse for all donations of medicines and medical supplies (WHO 1994). The guide-

lines are specific for the situation, listing criteria for the acceptance of donations and for necessary documentation, labeling, and packaging.

In 1996, WHO concluded a worldwide consultative process with more than 100 participants to develop *Guidelines for Drug Donations*, in close collaboration with the United Nations High Commissioner for Refugees (UNHCR), United Nations Children's Fund (UNICEF), the Red Cross, and nongovernmental organizations. The Partnership for Quality Medical Donations, which is a coalition of industry and relief groups, also supports the guidelines.

### 15.4 Guidelines for pharmaceutical donations

WHO carried out an assessment of first-year experiences with the 1996 guidelines (WHO 2000a) and published revised guidelines in 1999. Although the assessment was positive for the most part, concerns were expressed about the clarity of the specific guideline on the shelf life of donated medicines, which was revised in the new edition (WHO/DAP 1999). The new guideline allows for direct donations of pharmaceuticals with a remaining shelf life of less than one year to specific health facilities, provided assurance can be given that the pharmaceuticals can be used prior to expiration. This requirement addresses the concern that legitimate donations were being delayed because of confusion in the original clause related to expiry.

The many problematic donations received during the aftermath of the 2004 tsunami in South Asia, as outlined in Country Study 15-2, indicate, unfortunately, that many donors are not heeding the guidelines.

#### Core principles

The first and paramount principle is that a donation should be intended only to assist the recipient, and all efforts should be made to maximize its positive effect. This principle implies that all donations should be based on an expressed need by the recipient and that unsolicited donations are to be discouraged. The second principle is that a donation should be given with full respect for the authority of the recipient and be supportive of existing government policies and administrative arrangements. The third principle is that no double standards should be applied: if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation. The fourth principle is that effective communication must be maintained between the donor and the recipient; donations should be based on expressed need and should not be sent unannounced.

If these core principles are adhered to, donations will usually be helpful rather than harmful, providing the specific guidelines on medicines selection, quality, presentation, packaging, and labeling in Box 15-1 are followed.

## Country Study 15-2 Tsunami-related donations of medicines and supplies

On December 26, 2004, a massive earthquake measuring 9.3 on the Richter scale triggered a tsunami that devastated eleven countries in South Asia. International donors were quick to respond with aid; however, as with previous humanitarian crises, the lack of coordination and knowledge about the actual needs of the population decreased the effectiveness of emergency aid and generated additional challenges to public health efforts rather than easing what might have been the biggest crisis the area had ever experienced.

In Indonesia, pharmaceutical donations seemed to cause more problems for government authorities than they helped the population. Although the government asked for no medicines, more than 4,000 tons of pharmaceuticals were received for a population of 2 million, according to an assessment conducted by *Pharmaciens Sans Frontières Comité International*. Of these donations, most were deemed inappropriate: 60 percent of the medicines were not on the Indonesian national list of essential medicines; 70 percent were labeled in a foreign language; and 25 percent had an inadequate expiry date. Of the medicines that were appropriate, some arrived in extremely large quantities that would not be used before they expired. Approximately 661 tons of the donated medicine needed to be destroyed at an estimated cost of EUR 2.4 million. Countries are often hesitant to refuse

donations because of a fear of offending donors, which only perpetuates the problem.

In Sri Lanka, relief workers requested a donation of intravenous antibiotics to treat infected wounds. Although the pharmaceutical manufacturer shipped the antibiotics quickly to a nonprofit consolidator working in Colombo, the shipment was initially delayed by bureaucratic procedure at the airport, and then it took additional time to get the medicines on their way to those in need. By the time any of the shipment made it into the affected regions, the perceived need had not materialized—perhaps because patients had died already or because of the difficulty in assessing the need in the midst of chaos. Although the Sri Lankan officials were grateful to receive “an antibiotic that can treat horrible infections you can’t treat with normal antibiotics,” concern existed about what would happen when the stockpile expired.

The *Pharmaciens Sans Frontières* assessors in Banda Aceh, Indonesia, concluded that in the years after the first publication of the *Guidelines for Drug Donations*, the quality of pharmaceutical donations in emergency situations had not improved. During disasters where resources and capacity are limited, donations can be not only useless, but even detrimental to the health of peoples affected and the economy of the recipient country.

Sources: Chase and Barta 2005; Mason 2005; PSFCI 2005.

### Special guidelines for pharmaceutical donations in emergency situations

In emergency situations, it may not be practical for potential donors to wait for a specific request from the recipient. In any case, however, all proposed donations should be approved by the recipient before they are sent.

In the acute phase of an emergency, or in the case of refugee populations without any medical care, sending a range of medicines and medical supplies that is specifically designed for the circumstances is preferable. The Interagency Emergency Health Kit, which has been widely used since 1990, contains medicines, disposable supplies, and basic equipment for a population of 10,000 for three months. Its contents are based on a consensus among the major international aid agencies (WHO, UNICEF, UNHCR, Red Cross organizations, Médecins Sans Frontières, and OXFAM). It is permanently stocked by several major international suppliers (for example, UNICEF and the International Dispensary Association) and can be available within forty-eight hours.

From the recipients’ point of view, a donation in cash for the local purchase of essential medicines is usually much more welcome than a donation in kind (assuming the local market is functional). Apart from being supportive of the activities of the local coordinating body, a cash donation is usually more cost-effective and also supports local industry. In addition, local prescribers and patients are usually more familiar with locally available medicines. A donation in cash also avoids the problem of the coordinating body having to prioritize long lists of needs according to what might or might not arrive.

### Special guidelines for donations as part of development aid

When pharmaceuticals are donated as part of development aid, more time is usually available to specify needs and to follow guidelines on pharmaceutical donations. Special care should be taken that the medicines and their specifications comply with the national pharmaceutical policy and are

### Box 15-1 Guidelines for pharmaceutical donations

These guidelines, developed by WHO and updated from the original 1996 guidelines, reflect consensus among the major international agencies active in humanitarian emergency relief: WHO, Caritas Internationalis, Churches' Action for Health of the World Council of Churches, International Committee of the Red Cross, International Federation of the Red Cross and Red Crescent Societies, International Pharmaceutical Federation, Joint United Nations Program on HIV/AIDS, Médecins Sans Frontières, Office of the United Nations High Commissioner for Refugees, OXFAM, Pharmaciens Sans Frontières, UNICEF, United Nations Development Programme, United Nations Population Fund, and the World Bank.

Many different scenarios exist for pharmaceutical donations. They may take place in acute emergencies or as part of development aid in nonemergency situations. They may be corporate donations (direct or through private voluntary organizations), aid by governments, or donations to single health facilities. And although there are legitimate differences among these scenarios, the basic rules for an appropriate donation apply to all. The guidelines describe this common core of good donation practices.

The guidelines aim to improve the quality of pharmaceutical donations, not to hinder them. They are not international regulations but are intended to serve as a basis for national or institutional guidelines, to be reviewed, adapted, and implemented by governments and organizations dealing with pharmaceutical donations.

#### Selection of medicines

1. All pharmaceutical donations should be based on an expressed need and be relevant to the disease pattern in the recipient country. Pharmaceuticals should not be sent without prior consent by the recipient.
2. All donated pharmaceuticals or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential medicines, or, if a national list is not available, on the WHO *Model List of Essential Medicines*, unless specifically requested otherwise by the recipient.
3. The presentation, strength, and formulation of donated pharmaceuticals should, as much as possible, be similar to those commonly used in the recipient country.

#### Quality assurance and shelf life

4. All donated pharmaceuticals should be obtained from a reliable source and comply with quality standards in both donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (WHO 2000c) should be used.
5. No medicines that were issued to patients and then returned to a pharmacy or elsewhere, or that were given to health professionals as free samples, should be donated.
6. Upon their arrival in the recipient country, all donated pharmaceuticals should have a remaining shelf life of at least one year. An exception may be made for direct donations to specific health facilities, provided that the responsible professional at the receiving end acknowledges that he or she is aware of the shelf life, and that the quantity and remaining shelf life allow for proper administration prior to expiration. In all cases, the date of arrival and the expiry date of the medicines should be communicated to the recipient well in advance.

#### Presentation, packing, and labeling

7. All pharmaceuticals should be labeled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should contain at least 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.
8. As much as possible, donated pharmaceuticals should be presented in larger-quantity units and hospital packs.
9. All pharmaceutical donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list that specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight, and any special storage conditions. The weight per carton should not exceed 50 kilograms. Pharmaceuticals should not be mixed with other supplies in the same carton.

### Information and management

10. Recipients should be informed of all pharmaceutical donations that are being considered, prepared, or actually under way.
11. In the recipient country, the declared value of a pharmaceutical 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.

12. Costs of international and local transport, warehousing, port clearance, and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance.

Source: WHO/DAP 1999.

in accordance with national treatment guidelines or common practice in the recipient country. Administratively, the pharmaceuticals should be treated as if they were procured: they must be approved for importation and use by the drug regulatory authority in the country, probably through the same simplified procedure that would apply for government tenders. They should be entered into the inventory and distributed through the existing distribution channels. If cost-sharing procedures exist, the donated pharmaceuticals should not automatically be distributed free of charge, and the donor should not insist on free distribution. A good example of a successful integration of donated pharmaceuticals into the regular pharmaceutical supply system is described in Country Study 15-3.

### Special guidelines for donations of medical and laboratory equipment and supplies

The same core principles and general guidelines that apply to donating pharmaceuticals also apply to donating medical and laboratory equipment and supplies. A key factor to consider is whether the recipient truly needs the equipment and has the expertise and the means to operate and maintain it. Generally, capital equipment should not be donated in emergency situations, unless the emergency situation is expected to be prolonged.

A donation implementation plan should include the availability of trained personnel for operation and maintenance as well as support for other resources for operation (manuals, reagents, and supplies) and maintenance (technical documentation and spare parts). In addition, plans must include detailed installation and commissioning procedures. Finally, any special requirements for the equipment should be communicated to the recipient. Such requirements may include air or water cooling; electrical power; water quality; mechanical layout or radiation or acoustic shielding requirements; or specialized software needed to install, operate, or maintain the equipment. Periodic inspection, maintenance, and calibration should be carried out. WHO offers guidelines that cover equipment and supply donations (WHO 2000b).

## 15.5 Implementation of a policy for pharmaceutical donations

In managing pharmaceutical donations, both recipients and donors need to act to ensure that appropriate donations are received and that good use is made of them.

### Management of pharmaceutical donations by the recipient

Recipient governments must play a role in managing donations. No matter how disastrous the situation, failure to be involved may make things worse. National guidelines and administrative procedures need to be defined, and any requirements need to be specified in as much detail as possible.

**Define national guidelines for pharmaceutical donations.** Recipients find refusing a donation that is already under way notoriously difficult. For this reason, prevention is better than cure. The key point is that recipients should indicate to their (future) donors what kind of assistance they are likely to need and how they would like to receive it. If this information is provided in a rational and professional way, most donors appreciate it and will comply. Therefore, recipients should first formulate their own guidelines for pharmaceutical donations based on the CMC or WHO guidelines or the summary given above. These guidelines should then be officially presented to the donor community. Only after the guidelines have been presented and published can they be enforced. The preparation and implementation of the national donation guidelines should include stakeholders at all levels of the country's pharmaceutical management system to ensure that local officials are informed about the guidelines.

**Define administrative procedures for pharmaceutical donations.** It is not enough for recipients to adopt and publish general guidelines on the selection, quality, and presentation of donations. Administrative procedures need to be developed by recipients for defining needs, receiving donations, distributing, budgeting, and perhaps refusing or

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destroying some goods. Procedures need to be developed to carry out the following actions—

- Define needs
- Prioritize among requirements
- Coordinate all pharmaceutical donations
- Decide what documentation is needed when a pharmaceutical donation is being proposed, and who should receive these papers
- Establish criteria for accepting or rejecting a donation
- Coordinate reception, storage, and distribution of donated pharmaceuticals
- Agree on whether the donor or the recipient will pay for transportation, warehousing, port clearing, and similar costs before the donation shipment arrives
- Agree on how donations are to be valued in budget and expenditure records
- Agree on charging for donated pharmaceuticals in the context of a public user-fee program
- Deal with donated pharmaceuticals not registered or included in the national essential medicines list in the country
- Supervise the distribution of donated medicines and supplies to prevent them from being diverted for

export, for commercial sale, or to illicit channels

- Dispose of worthless donations

**Specify the needs for donated pharmaceuticals.** Recipients must also provide donors with as much specific information on medicine needs as possible. This requirement puts the onus on the recipient to prepare requests carefully, indicating quantities required and prioritizing the items. The more information that is given, the better. Openness about donations that are already in the pipeline, or anticipated, is helpful to donors. It is always greatly appreciated and pays off in the long term. Recipients are entitled to the same openness from donors with regard to pharmaceutical donations that are in the pipeline.

### Good practices for donors

Donors should always respect the four core principles listed in section 15.4. Donors should also respect the guidelines issued by the recipients and respond to the priority needs they have indicated. Donor-driven donations should always be discouraged, particularly donations that are initiated by international pharmaceutical companies to obtain tax advantages or donations of returned medicines or samples.

### Country Study 15-3

#### Integrating pharmaceutical donations into the Mongolian supply system

After the collapse of the former Soviet Union, Mongolia became one of the countries where a large proportion of medicine consumption is covered by pharmaceutical donations. Such donations are treated as regularly procured pharmaceuticals.

Upon the arrival of a donation, all papers are sent to the Ministry of Health for clearance of the import. If the medicines are accepted, an import price is decided on by a special unit in the ministry. This price is normally equal to the last tender price for the same product or a price taken from Management Sciences for Health's *International Drug Price Indicator Guide*. Many donors are valuing their donations at a much higher price—for example, retail price in the donor country—but this price is not accepted as a reference. If a product that is not on the Mongolian essential medicines list is accepted, it is given a price equivalent to that for a similar medicine on the list, irrespective of the price in the donor country.

The value of the pharmaceutical consignment is entered into the accounts of Mongol Emimpex, the state wholesaler. Then a selling price is set for each medicine by adding a 15 percent markup for the wholesaler and 23

percent for the pharmacist. These markups cover all expenses for control and distribution. The (assigned) import value is kept on a separate account and transferred to a fund controlled by the Ministry of Health for future pharmaceutical procurement.

The main benefit of this system is that it is sustainable and not destructive to the existing pharmaceutical supply system. In many other countries, uncontrolled sales of donated pharmaceuticals are well known to take place, and the money is pocketed by health personnel. In Mongolia, the system is completely transparent. All pharmaceuticals coming into the country are for sale, and the donors are assured that their import value goes back to the revolving fund.

The only drawback of the system is that even the neediest customers—patients or health institutions—have to pay for donated pharmaceuticals, and they may not be able to do so. However, the case would be the same with normal pharmaceutical procurement and has to be solved by health insurance systems or specific government support to the needy.

Source: WHO/DAP 1999.



DONATIONS CAN THEMSELVES BE A DISASTER AREA

The public at large in the donor country is usually not aware of common problems with pharmaceutical donations. The government should therefore make some effort to create more public awareness of donors' responsibilities. The best moment for this publicity is probably at the time of the public appeal through the media, when the government is requesting funds.

At the country level, would-be donors are usually counseled to choose a "lead donor" among themselves to coordinate their actions and sometimes also to act as a central contact point in discussions with the recipient government. Some organizations act as coordinators/consolidators for international pharmaceutical donations. For example, the German association of research-based pharmaceutical companies matches requests from ministries of health and international relief agencies with donations from German pharmaceutical companies to maximize the usefulness and efficiency during emergency situations.

As previously mentioned, the recipient country should supply as much information as possible on requested and approved donations. But the donors themselves should also inform the recipient well in advance and in detail about what donations are coming, and when. This information will greatly assist the coordinating body in the recipient country in planning for the proper reception of the donations and in

identifying the need for additional supplies. Although the landscape of pharmaceutical donations is complex, assessments have shown that, when handled with care, the donation process can help satisfy local medical needs (Reich 1999).

### 15.6 Donations as part of public-private partnerships

Although the focus of pharmaceutical and medical supply donations is on cases of disaster or other emergency, a number of public-private partnerships are built on using existing products to address specific health conditions. Examples of such programs include the albendazole donation program to fight lymphatic filariasis and the Zithromax program to prevent blindness from trachoma. The Axios Foundation administers such programs for pharmaceutical companies, providing technical assistance to facilities in least-developed countries (see, for example, <http://www.accesstotreatment.org> and <http://www.pmtctdonations.org>). Although pharmaceutical companies generally sponsor donation partnerships to help get a particular medicine to those who need it, the partnerships are also part of the companies' goal to publicize social responsibility through philanthropy.

Pharmaceutical companies have spent millions of dollars on donations, and although countries can certainly benefit from the additional resources for targeted programs, the partnerships are not trouble-free. For example, costs are associated with pharmaceutical donation programs, such as distribution, storage, and training health workers. The public sector may be expected to handle those costs, possibly at the expense of other health programs, including the diversion of human resources. In addition, a partnership that targets only a specific country or commits to a specific time period may be depriving other needy countries or patients who will not have access to the medicines after the partnership commitment is completed. Product-based donation programs are generally difficult to sustain without an open-ended commitment or a commitment to eradicate a containable disease, and such programs often fill only a small part of the actual need.

Merck's Mectizan program operates in all countries where onchocerciasis is endemic and where filariasis is co-endemic and is supplying the medicine until the diseases are eradicated. Because onchocerciasis is limited in geography, has a simple treatment protocol, and can be eradicated, an open-ended donation program is feasible. On the other hand, most disease-specific initiatives target only select countries where the disease is endemic and usually commit to a limited initial time frame (Buse and Walt 2000b).

The Malarone donation program in Kenya is an example of a public-private partnership undermined by dissatisfaction among stakeholders about how well their individual interests were represented. Eventually, the partners clashed over accountability and ownership of the program (Shretta et al. 2001). Furthermore, incorporating the donated Malarone into the public health treatment guidelines and national pharmaceutical policy caused confusion and conflict. Ultimately, there was concern that the failure of the Malarone donation program could discourage other corporate philanthropy and taint the view of public-private partnerships.

When entering into public-private health programs based on pharmaceutical donations, recipient countries must be fully involved with the planning and implementation of the program (Buse and Walt 2000a), and the donor organizations should follow the core principles of donating pharmaceuticals or medical supplies. ■

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## ASSESSMENT GUIDE

### Indicators of policy

- Is there a national policy on donations of pharmaceuticals and medical and laboratory equipment and supplies?
- What are the differences between the national policy and the WHO policy on pharmaceutical donations?
- Is there a set of administrative procedures for managing pharmaceutical donations?
- Do pharmaceutical donations comply with the national list of essential medicines?
- Does the ministry of health have control over which medicines and supplies will be accepted?

### Extent of pharmaceutical donations

- What is the value of international aid received for pharmaceuticals (cash and in-kind donations) compared with the value of the public pharmaceutical budget spent?

### Implementing pharmaceutical donations

- Who coordinates all pharmaceutical donations?
- Which documents are needed when a donation is planned; who should receive them?
- What are the criteria for accepting or rejecting a donation; who makes the final decision?
- What procedure is used when donations do not follow the guidelines?
- Who coordinates reception, storage, and distribution of the donated pharmaceuticals?
- How are donations valued and entered into the budget/expenditure records?

- How will inappropriate donations be disposed of?

### Problems with pharmaceutical donations

- What are the main problems with pharmaceutical donations?

### Needs assessment for donors in an emergency

- What is the nature of the event, its effects, expected duration, expected amount of time the population will be displaced or affected?
- What are the demographics and socioeconomic status of affected populations?
- What is the status of the existing health care infrastructure and availability of transportation to existing health care sites?
- Are human resources available to take responsibility for and to appropriately dispense prescription medication?
- What are the recipients' customary modes of treating diseases?
- What are the affected area's location, accessibility, climatic conditions, and security status?
- What are the rules and regulations of local recipient governments?
- Are contacts in place for key ministry of health or other country personnel?
- How receptive are local authorities to foreign humanitarian operations in their country?

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