

To give is better than to receive: compliance with WHO guidelines for drug donations during 2000–2008

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Objective To assess drug donations in terms of their adherence to the drug donation guidelines put forth by the World Health Organization (WHO).

Methods In 2009 we searched the academic and lay literature – journal articles, media articles and industry and donor web sites – to identify reports about drug donations made from 2000 to 2008. Publications focusing on molecular mechanisms of drug action, general descriptions of guidelines or specific one-time drug donations before 2000 were excluded. For cases with sufficient information, we assessed compliance with each of the 12 articles of WHO's guidelines.

Findings We found 95 articles describing 96 incidents of drug donations between 2000 and 2008. Of these, 50 were made in response to disaster situations, 43 involved the long-term donation of a drug to treat a specific disease and 3 were drug recycling cases. Disaster-related donations were less likely to comply with the guidelines, particularly in terms of meeting the recipient's needs, quality assurance and shelf-life, packaging and labelling, and information management. Recipient countries were burdened with the costs of destroying the drugs received through inappropriate donations. Although long-term donations were more likely to comply with WHO guidelines related to quality assurance and labelling, they did not consistently meet the needs of the recipients. Furthermore, they discouraged local drug production and development.

Conclusion Drug donations can do more harm than good for the recipient countries. Strengthening the structures and systems for coordinating and monitoring drug donations and ensuring that these are driven by recipient needs will improve adherence to the drug donation guidelines set forth by WHO.

Une traduction en français de ce résumé figure à la fin de l'article. Al final del artículo se facilita una traducción al español. الترجمة العربية لهذه الخلاصة في نهاية النص الكامل لهذه المقالة.

Introduction

Drug donations are pharmaceutical agents given to countries or health facilities at no cost by nongovernmental organizations (NGOs), other countries, private corporations or groups of donors. The donations may be made for different purposes, such as providing assistance during emergency situations, supplying specific medicines over the long term or recycling drugs (e.g. donating leftover drugs just before they expire if a clinic purchased more than it actually needed). Although the sources and reasons for drug donations differ, the same basic guidelines apply to drug donations of all types.^{1,2}

Drug donations are intended to provide the medicines needed to alleviate suffering, yet drug donations often generate problems.² For example, the donated drugs may not meet the needs of the recipient and donor agencies may fail to comply with local procedures for approving, labelling, storing or inventorying medicines. The donated drugs are often also labelled in a language foreign to the recipient population, they may fail to meet the quality standards established by the recipient country or they may even have expired. Lastly, drug donations can be a financial burden on the recipient country. If the donated drugs have a high declared value, import taxes and overhead costs may be high; if the quantity of the donation is larger than required to meet the recipient's needs, the recipient may have to bear the cost of properly disposing of the excess.

In 1996, the World Health Organization (WHO), in collaboration with major international agencies active in humani-

tarian relief, issued guidelines aimed at reducing the problems that are often linked with drug donations.¹ Following review, the guidelines were revised and reissued in 1999.² Because the guidelines were developed from the standpoint of providing aid to countries who are in need of drugs, the donations are guided by four core principles: They must be: (i) of maximum benefit to the recipient; (ii) given with respect for the recipient's wishes and authority; (iii) free from any double standards in product quality; and (iv) provided through effective communication between donor and recipient. The 12 articles of the guidelines on drug donations are based on these four principles. The guidelines are applicable to both emergency and long-term donations.

The objective of this study was to assess the level of adherence to the 1999 edition of the WHO *Guidelines for drug donations*² by reviewing all the drug donation cases that have occurred from 2000 to 2008.

Methods

In 2009 we searched the academic and lay literature to identify reports about drug donations from 2000 to 2008. We searched PubMed and Google Scholar using the terms “drug donation(s)” and “program(s)(me)(mes)” and performed snowball searches based on the names of specific products, companies or events associated with drug donations as we found them. For example, when we found an article mentioning drug donations in response to an earthquake in Gujarat, we specifically searched for articles on this event (earthquake) in that location (Gujarat). We also

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searched the WHO Library (www.who.int/library/en/), Intranet (www.who.int/en/), Internet (www.who.int/en/) and Essential Medicines and Pharmaceutical Policy (<http://www.who.int/medicines/en/>) using derivatives of the phrase “drug donation”. A snowball search of web sites mentioned in these initial searches, including web sites of pharmaceutical companies and NGOs, was conducted. We also posted a request for any relevant articles on eDrug (www.essentialdrugs.org), an electronic information source on essential drugs. When particular cases were identified, we queried for more information on them by using keywords that were specific to each event. All case studies, news reports, journal articles and company reports that were available were considered for inclusion. Publications about the molecular mechanisms of drug action or general descriptions of guidelines were excluded. Reports or articles describing specific one-time drug donations before 2000 were excluded, but no year restriction was placed on long-term donation or drug recycling programmes.

All incidents of drug donations were recorded and categorized by date, recipient country, type of pharmaceutical agent(s) donated (mix of medicines, specific products), donor(s), donor type (NGO, corporation, government, other) and type of donation (emergency aid following a disaster, part of a long-term programme or part of a drug recycling programme.) Incidents that had sufficient documentation describing the details of the donation were used to assess compliance with the 12 articles in WHO's *Guidelines for drug donations*.² We report the percentage of the donations that were in compliance with those articles for which information was provided, stratified by type of donation.

Results

We identified 268 relevant articles but excluded 173 of them because they mentioned drug donations in passing. The remaining 95 included articles describing 96 incidents of drug donations between 2000 and 2008; 50 occurred in disaster situations, 43 were long-term donations and 3 were part of drug recycling programmes. Of the 50 donations for disaster situations, 13 were made through NGOs and 13 had unspecified donors. Of the 43 long-term donations, 40 involved the long-term supply of a drug to treat a specific disease, 3 were made for extended

Table 1. Location and date of disaster-related drug donation cases found in study of compliance with World Health Organization drug donation guidelines, 2000–2008

Disaster	Location	Date
Cyclone	Myanmar	2008
Earthquake	Indonesia (Java)	2006
War	Iraq	2006
Earthquake, tsunami	Indonesia (Nias)	2004, 2005
Earthquake	Pakistan	2005
Tsunami	Sri Lanka	2004
Tsunami	Indonesia (Aceh)	2004
Earthquake	El Salvador	2001
Earthquake	India (Gujarat)	2001
Post-war conflict	Timor-Leste	1999–2001
Floods	Mozambique	2000
Floods	Bolivarian Republic of Venezuela	2000

disaster relief, and 3 were made for the purpose of recycling the drugs. Of these 43 donations, 18 were carried out through NGOs, but we were unable to determine if the drugs had been donated to or purchased by the NGO.

We had sufficient information about 29 donations to expand them into case studies: 12 donations were disaster-related, 14 were for the long term and 3 were intended for drug recycling.

Disaster-related donations

Table 1 summarizes the characteristics of the disaster-related donation case studies. The published reports of these cases did not provide enough information to assess compliance with each of the 12 articles of the WHO drug donation guidelines.

Selection of drugs

The most frequently reported problem linked to disaster-related drug donations was a failure to meet the needs of the country. Five of the 12 recipient countries involved had compiled a list of the medicines they needed, yet two such countries reported that the majority of the donated drugs were unsolicited, unnecessary or insufficient. In only one disaster (Gujarat, India) did the majority of donations correspond to needed medicines on the list the country had provided.³ Of the 12 countries that experienced disasters, three were sent medicines without their prior approval. In the case of the United Republic of Tanzania, the recipient reported that communication with the donors had been poor and that some of the drugs received were unsolicited.⁴

Some recipient countries attempted to reject donations they considered in-

appropriate, but not all were successful. Several donations prompted by the war in Iraq were rejected because they did not conform to WHO guidelines.⁵ Although El Salvador had established an information management system to monitor and potentially reject drug donations, coordination among donors was not completely successful after the 2001 earthquake and only 63% of the medicines received met the needs of the country.³ Donors are becoming more aware of proper donation practices. After the 2006 earthquake in Java, Indonesia, the international health partners waited for requests for medical donations from the country and ultimately did not send any as the needs could be met locally.⁶ In the case of Gujarat, the medicines donated had been approved by an Indian regulatory authority,³ whereas in Sri Lanka, 40% of the donated medicines had not been approved.⁷

Mozambique was the only recipient country where all of the donated drugs were on the national list of essential medicines.³ In Sri Lanka and Aceh, Indonesia, few of the donated medicines were on this list.^{7,8}

Quality assurance and shelf-life

In 3 of the 12 cases of disaster-related donations, the donated medicines had expired or did not meet the WHO guideline requiring a remaining shelf-life of at least one year or, in exceptional cases, of at least one-third of the drug's total shelf-life at the time of donation. In contrast, the majority of the drugs donated to Gujarat had not expired.³

Presentation, packaging and labelling

The other most frequently reported problem with disaster-related drug donations

was improper labelling, which was documented in three cases. The labelling was inappropriate because either the information provided was insufficient to identify and use the drug, the labels were in a language not spoken in the recipient region or the package inserts were missing. In addition, the donated medicines were often unfamiliar to local health-care workers. Whereas in Gujarat the donated medicines were labelled like others used previously in the country, in Sri Lanka most of the donated medicines were unfamiliar.^{3,7} If health workers do not understand how donated drugs should be used, disaster victims can be harmed. This occurred in Sri Lanka, where a young boy suffered throat damage after being given an oral dose of a chemical for cleaning wounds.⁷ However, the case of Gujarat shows that donations can be effective; the drugs were purchased locally and then donated, and 95% of them were correctly labelled and appropriate for the needs.³ Two countries reported that because the medicines were not delivered in large-quantity packs or hospital packs, they were insufficient for hospital use. A Sri Lankan report also indicated that many samples had been received,⁷ and some drugs donated to the United Republic of Tanzania also consisted primarily of samples, some of which had been partially used.⁹

Information and management

In four of the 12 disaster-related drug donation cases, emergency preparation plans or systems were in place to handle disaster relief activities. This facilitated coordination in dealing with the event in three cases, but in Mozambique the emergency plan was inadequate for the extensive flooding that occurred.³ In five of the 12 cases there were local supplies of buffer stocks, and in four instances these buffer stocks were useful during the immediate aftermath of the event. However, in Mozambique they were destroyed by the floods and the country became dependent on donations to meet its medical needs. However, even though essential medicines were donated, 75% of them did not meet requirements for storage, labelling and packaging.³

In three cases the majority of the drugs donated were appropriate but excessive. The immediate effect of excessive, unorganized donations is to overwhelm the aid workers of the recipient country. In two such cases the arrival of all the do-

nations in too short a time period made it difficult to inventory, store and handle the drugs. In the Bolivarian Republic of Venezuela, extra workers were hired at government expense to sort and store the drugs donated following severe floods.¹⁰ In Mozambique, incoming drug shipments had to be moved to nearby warehouses until they could be properly assessed and sorted.³ In the United Republic of Tanzania, the costs of transporting and processing the donations were not paid by the donors and exceeded the value of the donated drugs.⁴

Donations that exceed local needs require large amounts of storage space, with a resulting risk of improper storage and of occupying space that could be used for shelter. Donations in response to the 2004 tsunami in Aceh, Indonesia, were stored in private homes, health centres, hospitals, schools and other public buildings. In two donation cases, the 2000 floods in Mozambique and the 2004 tsunami in Sri Lanka, the medicines were damaged because they remained in warehouses for long periods under conditions that did not comply with recommended storage practices. Following the Sri Lankan tsunami, extra storage space in Colombo was rented and the Ministry of Health had to bear all costs for the transport, storage and handling of the donated medicines.⁷ There is evidence suggesting that in Sri Lanka improper storage of an anaesthetic agent left over from a donation in 2005 led to contamination with *Aspergillus fumigatus* and to the death of three pregnant women who contracted nosocomial meningitis after receiving spinal anaesthesia for Caesarean sections.⁷

After the disasters, any excess drugs received were either destroyed or kept in health facilities for later use, but the reports provide no indication that the related costs were covered by the donors. The cost to the recipient countries of destroying leftover drugs after the tsunami amounted to 26 039 United States dollars (US\$) in Sri Lanka (2007)⁷ and to US\$ 3 420 000 in Aceh, Indonesia (2005).⁸

Donated medicines that remain within a recipient's health-care system can harm local pharmaceutical industries and the economy. Aceh received an estimated 4-year supply of tetracycline and a 6-year supply of dextromethorphan. Both donations were excessive and the drugs could have been purchased from local pharmaceutical companies.⁸

Case example: good compliance

Donations following the 2001 earthquake in Gujarat, India, complied with WHO drug donation guidelines in terms of drug selection, quality assurance and shelf-life, presentation, packaging and labelling and information and management. Prior to the earthquake, this region of India had an established disaster management system for receiving medical assistance, and the system included an essential drugs list and a defined organization scheme for handling medicine donations from the centre to the periphery. A local buffer supply of essential medicines was available for immediate aid. After the earthquake, medical needs were assessed by the government and NGOs and a public request for needed medicines was made through the media. This served as a guideline for donors and for drug distribution in the area. Medical personnel were deployed in large numbers to handle donations. Of the drugs donated, which totalled 1308 tonnes, 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 most of them had come from other parts of India. Yet despite the fact that most donations were in compliance with WHO drug donation guidelines, the amount donated far exceeded the need. Consequently, India had to pay for destroying the excess drugs.³

Case example: poor compliance

The response to the tsunami that affected Sri Lanka in 2004 stands as an example of poor compliance with WHO drug donation guidelines. Although Sri Lanka did express the need for specific medicines, as indicated by the guidelines, donors failed to comply with the guidelines on matters of quality assurance and shelf-life, presentation, packaging and labelling and information management. Following the tsunami, medical assistance was received 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 Sri Lanka's Ministry of Health issued a needs-based list of requested medications, many donations were inappropriate or appropriate but excessive. Of the drugs received, totalling 56 tonnes, only 10% were on the list of requested medications. More than 80%

Table 2. **Drugs, target diseases and donors involved in long-term drug donations found in study of compliance with World Health Organization drug donation guidelines,² 2000–2008**

Generic drug (brand name)	Disease	Donor
Trovafloxacin (Trovan [®])	Meningitis	Pfizer
Azithromycin (Zithromax [®])	Trachoma	Pfizer
Albendazole (Albenza [®])	Intestinal helminthiasis lymphatic filariasis	GlaxoSmithKline
Imatinib (Glivec [®])	Chronic myeloid leukaemia or gastrointestinal stromal tumours	Novartis
ACT: artemether and lumefantrine (Coartem [®])	Malaria	Novartis
Ivermectin (Mectizan [®])	Onchocerciasis	Merck & Co.
Ivermectin (Mectizan [®])	Lymphatic filariasis	Merck & Co.
Atovaquone (Malarone [®])	Malaria	GlaxoWellcome
α -difluoromethylornithine, melarsoprol and pentamidine	Human African trypanosomiasis	Sanofi-Aventis
Praziquantel (Cesol [®] 600)	Schistosomiasis	Merck & Co.
MDT: dapsone, rifampicin (Rimactane [®]) and clofazimine (Lamprène [®])	Leprosy	Novartis
Mebendazole	Helminthiasis	Johnson & Johnson
Nevirapine (Viramune [®])	HIV infection (prevention of mother-to-child transmission)	Boehringer Ingelheim
Fluconazole (Diflucan [®])	Cryptococcal meningitis	Pfizer

ACT, artemisinin-based combination therapy; HIV, human immunodeficiency virus; MDT, multidrug therapy.

were unsolicited, unexpected and unsorted. Of the donated drugs, 43% were not essential medicines and 38% were never registered for use in the country. Labelling was largely inappropriate; 62% of the medicines were labelled in languages not readily understood, 15% bore no generic name and 81% had no package insert. The expiry date was not shown on the label of 50% of the drugs; 6.5% of the medicines expired on arrival and 67% expired within less than a year. Donations were largely uncoordinated, since 50% were unused drugs collected from private donors and 86% came from individuals. In contrast, 90% of donations from governments were relevant to the needs of the recipient country. Because some donations were excessive, between 20 and 30 tonnes of drugs were stored in rented storage sites or in a variety of facilities where storage conditions were unsuitable for maintaining drug quality. Furthermore, the excess donations strained existing human resources, since the excess drugs had to be received, processed and distributed. Some financial donations were equivalent to 50% of the Sri Lankan health budget, but the funds were spent on expensive drugs manufactured outside the region of south-east Asia. In addition, the Sri Lankan Ministry of Health had to pay the costs of handling, transporting and storing the donations and of destroying 150 metric tonnes of excess medicines (at US\$ 120 to US\$ 180 per metric tonne).⁷

Long-term donations

Of the 43 long-term donation reports, 14 provided sufficient information to constitute case studies (Table 2). In the majority of these cases, the donors indicated that they had complied with WHO drug donation guidelines in general but gave no detailed information about compliance with each of the 12 articles in the guidelines.

Selection of drugs

None of the long-term donation programmes originated in response to a specific request from a country; instead, most of them were created to target diseases that are endemic in very large territories. However, the medicines supplied by the programmes have not been equitably distributed for various reasons. Imatinib (Glivec[®]) was donated worldwide (81 countries) by Novartis for chronic myeloid leukaemia or gastrointestinal stromal tumours. In this case, patients found the application process difficult and a hindrance to receiving the drug,¹¹ a reflection of the fact that the regulatory status and clinical acceptance of a drug can affect the success of a donation programme. Patients from countries where a particular drug is considered a first-line treatment for the targeted condition may be accepted into a donation programme more readily than patients from countries where this is not the case. This may explain why imatinib (Glivec[®]) has been donated to more individuals in the United States of America

than in other countries.¹¹ Nine of the long-term donation programmes in this study involved drugs listed on the 2009 WHO essential medicines list.

Presentation, packing and labelling

Some of the treatments donated under long-term programmes are complicated for the patient to take or may be experimental in nature. For its anti-leprosy donation programme, which is based on a fixed-dose drug combination, Novartis wisely organized the medicines into blister packages containing one full treatment course.^{12,13} By contrast, Kenya was reluctant to participate at the national level in the GlaxoWellcome atovaquone (Malarone[®]) donation programme because the medicine had not received regulatory approval in the country and was considered experimental.¹⁴ A pilot programme in the Siaya district was launched, however. Five of the programmes in the case studies had launched training activities for health-care workers in the targeted regions. None of these case reports contained information about the language in which the medicine packages were labelled.

Information and management

Coordination among different donation programmes is important. Long-term programmes target overlapping areas, mostly in Africa. Nine of the programmes were conducted through partnerships with NGOs, foundations or other enti-

ties, which facilitated programmatic coordination. In one case study, Merck, the maker of ivermectin, and GlaxoSmith-Kline, the maker of albendazole, successfully cooperated to deliver combination treatment for lymphatic filariasis. This partnership has been in existence for over 10 years and is pledged to continue as long as necessary.¹⁵

If multiple long-term donation programmes within a region are not adequately monitored, the same individuals could be inadvertently enrolled in several clinical trials and suffer the effects of drug interactions. Studies that have been conducted to test the effect of simultaneously taking the drugs donated under different programmes have shown that azithromycin, ivermectin, albendazole and praziquantel can be safely taken in combination.

Donated drugs may sometimes be used for purposes other than those for which they were donated. For example, praziquantel is currently being donated for schistosomiasis in 33 African countries, including Angola, Benin, Cameroon, Central African Republic, Madagascar and Senegal, which have been designated by WHO for priority control of neglected tropical diseases. In the 2009 version of the WHO list of essential medicines it is also indicated for the treatment of other intestinal helminthiasis, which raises the possibility of using this widely donated medicine for other indications.¹⁶

Other concerns

Long-term donations are implicitly expected to last until they are no longer needed. Of the 14 long-term donation cases we identified, 10 are still in effect. In 7 of these cases, the donors have pledged to continue to donate the drugs until the disease is either eliminated or under control. In the case of the GlaxoWellcome atovaquone (Malarone[®]) donation, the programme was suspended after two years because the company could no longer support it.¹⁷ Pfizer ceased to donate trovaflozacin (Trovan[®]) following a Nigerian lawsuit in which the drug allegedly killed 11 children and left dozens disabled.¹⁸ Of the 10 ongoing donations, nine involve partnerships between organizations for support and funding. The gift of multidrug therapy for leprosy by Novartis is the only non-partnership donation programme in which the donor company has covered the excess costs generated by the donation.^{12,13}

As previously mentioned, the sale of donated drugs within recipient countries can reduce the local production or sale of an equivalent product. In four of the case studies – albendazole, imatinib, malarone and azithromycin – the drug donated over the long term was also sold in the recipient countries. In two cases, companies declined donating drugs to countries that manufactured or imported a similar product. Novartis suspended its imatinib (Glivec[®]) donation programme prematurely in one country because one local company violated patent rights.¹¹

Case example: good compliance

Merck's ivermectin (Mectizan[®]) donation programme, which has been in effect since 1988, shows good compliance with WHO drug donation guidelines. It meets existing needs and complies in terms of quality assurance and shelf-life, presentation, packaging and labelling and information management. Users are educated about the product and the results of treatment are monitored. In collaboration with the WHO African Programme for Onchocerciasis Control (APOC) and the Onchocerciasis Elimination Program for the Americas (OEPA), in 1988 Merck began to provide ivermectin (Mectizan[®]) to treat onchocerciasis (river blindness) in communities located in 35 African and Latin American countries and in Yemen.¹⁵ This drug later came into use as a component of combination therapy for lymphatic filariasis, and Merck accordingly donated it to 11 countries in Africa and to Yemen for this indication. Merck distributes the medicine as part of a community-based programme that also provides vitamin A, eye care services and insecticide-treated bednets. The community decides whether it wants to participate in the programme, how the drug will be collected and distributed and how progress will be monitored. Supervision and training are provided by external health workers. Merck has pledged to continue the donations until the targeted diseases are eliminated.¹⁹ Prior to the donation programme in 1988, the rate of infection with *Onchocerca volvulus* was greater than 60% in some areas and the resulting rate of blindness was as high as 10%. There was also a high rate of transmission. The percentage of the eligible population that gets treated is estimated at 65% by APOC and at more than 85% by OEPA. In the American continent onchocerciasis has been reduced by 86%.²⁰ Programme sustainability depends on

continued support for drug distribution in the form of financial aid and regional resources, such as health workers for community training.

Case example: poor compliance

Novartis's imatinib mesylate (Glivec[®]) donation programme, also known as the Glivec[®] International Patient Assistance Programme, exemplifies poor compliance with WHO drug donation guidelines. Although the programme meets the guidelines with respect to quality assurance, presentation, packaging and labelling, it fails to comply with them on drug selection and compatibility with the recipient's expressed needs. Novartis created the programme to benefit patients with chronic myeloid leukaemia or gastrointestinal stromal tumours anywhere in the world,²¹ yet countries have not benefitted equally. The drug has reached 2000 patients in the United States as opposed to only 1500 in all other countries combined.¹¹ Glivec[®] is an effective but expensive chemotherapeutic agent and Novartis has structured the donation programme as a tiered system in which only those who can afford the drug have to pay for it. The programme has been criticized as inequitable because of this tiered pricing system, its complicated application process and the fact that Novartis will not donate Glivec[®] unless it is recommended by local guidelines, a condition that expands the paid market for the product. Furthermore, Novartis will not donate the drug to countries that manufacture a generic equivalent. This gives Novartis a monopoly over the market and increases its profits. Novartis suspended its imatinib donation programme in India when national pharmaceutical companies began producing the generic product.²²

Recycling donations

The AID for AIDS recycling programme in the United States, which started in 1996, collects unused drugs for HIV infection and distributes them through regional offices in South and Central America. Regional offices also maintain a small stock of medicines to meet emergency needs. The donated medicines must be unopened or tamper proof, properly transported and stored, and appropriately labelled. However, the drugs can be distributed up to six months after their expiration date.²³ Recycling programmes in Tulsa, Oklahoma, and San Mateo, California, collect a variety

of unused medicines to distribute to low-income patients in hospitals or nursing homes.^{24,25} The medicines are inventoried and stored in pharmacies, they must be unopened or tamper proof and they must not have expired.

Discussion

We found several donations that did not comply with WHO drug donation guidelines, and they were mostly in response to emergency situations. The results of this review suggest that WHO guidelines for drug donations require no substantial changes but that they need to be enforced more strictly. One important barrier to enforcing the guidelines in emergency situations is the lack of an infrastructure for monitoring incoming medicines. Our findings highlight the importance of conducting empirical field work and real-time monitoring after health interventions, including drug donations. Such “post-donation surveillance” is necessary to determine if a donation is doing more good than harm or vice versa. A system for monitoring and evaluating all drug donations is essential because the information obtained from media coverage may be largely focused on uncommonly beneficial or problem-ridden drug donations and hence biased. Establishing an independent registry of drug donations would facilitate coordination, monitoring and compliance with WHO drug donation guidelines. The registry should include a checklist for adherence to each of the 12 articles in these guidelines. An example of such a system is the Donations of Medicines Eligibility Program, launched by the Canadian International Development Agency (CIDA) in 2008. CIDA monitors all drug donations and assesses compliance with WHO guidelines.²⁶

WHO's drug donation guidelines were developed to help countries manage drug donations. However, recipient countries should formulate their own national drug donation guidelines to avoid receiving unnecessary medicines.¹ Countries in need of drug donations should provide a list of medicines as recommended in their guidelines, along with a list of any financial or human resources needed to store, transport or dispense the medicines. Recipient countries could also publicly request cash rather than drug donations. Guideline implementation could perhaps be improved by providing

recipient countries with a mechanism for declining donations. Countries that accept donations should require that any unused or unusable portion of the donation be removed from their territory and properly disposed of by the donor. To better plan for receiving actual donations, countries could perform “virtual” donation exercises as part of their disaster preparedness activities. Good coordination among donors was a feature common to the most successful donations. To avoid being burdened with unnecessary or unusable medicines, donation recipients could demand that donors work together or through coordinating NGOs.

Donors consistently ignore the WHO guideline indicating that the donor should bear the costs of sorting, storing, distributing and destroying products donated in excess. By having to cover these costs, donors would become more aware of the problems faced by the recipient countries and strive for better coordination. The Pan American Health Organization's recommendations for humanitarian aid provide additional guidance for drug donors.²⁷ They include using locally-produced medicines as a priority; advising the media not to issue requests for medicines, and discouraging donations from individuals to avoid receiving expired, unsorted, open or partially used products.

WHO drug donation guidelines also apply to long-term donations of specific products. Such donations tend to comply with WHO guidelines better than disaster-related donations, particularly with respect to product quality and data management. The reason may be that long-term donations are made by pharmaceutical companies with good systems in place for quality assurance and monitoring, whereas donors responding to disaster situations tend to collect and distribute medicines without conducting quality assurance checks or coordinating their efforts. Long-term drug donations could be detrimental for recipient countries. They may fail to meet the countries' needs or encourage the use of newer, more expensive brand-name products. In addition, if the drug donated over the long term is not an essential medicine, the donation can contribute to the inequitable distribution of expensive drugs. On the other hand, long-term donations that are not sustained fail to provide patients with consistent treatment. To qualify for long-term drug donation programmes,

countries should not have to impose manufacturing restraints on their national pharmaceutical industries. As noted by Lucas, WHO drug donation guidelines could be modified so as to recommend that companies involved in long-term drug donations provide assurance of their sustained commitment and effectively manage their donation programmes through collaboration with partners.²⁸

This study has several limitations. Our data sources were primarily peer-reviewed journal articles, media reports and company web sites describing drug donations. These sources may provide biased information, since the lay press tends to focus on donations that have given rise to problems, whereas company web sites highlight donations that have proved beneficial. As our search was limited to the English-language literature, we may have missed press reports written in the national languages of recipient countries. None of our sources provided enough details about each donation to assess compliance with every one of the 12 articles in the WHO drug donation guidelines. To obtain balanced and comprehensive information about drug donations, more in-depth country reports, such as the report from Sri Lanka, would be useful.⁷ Although we systematically included in our study drug donations from 2000 to 2008, more recent donations, such as the provision of medical supplies to Gaza in 2009, suggest that compliance with WHO guidelines remains poor.²⁹

On the surface, drug donations are appealing because they satisfy the human drive to help those in need. Donors are generally well intentioned and genuinely believe in the importance and value of their donations. However, they need to realize that donations are not always in the best interests of the recipient countries. While the needs of the donor may be met, the needs of the recipients often go unsatisfied. In fact, disaster-related drug donations may hinder rather than facilitate recovery. Even donations that comply with most WHO drug donation guidelines can be detrimental to recipient countries. Strengthening the structures and systems required for the coordination and monitoring of drug donations, which should be driven by recipient need rather than by charitable intentions, will improve adherence to WHO drug donation guidelines. ■

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مخلص

اليد العليا أفضل من اليد السفلى : الالتزام بالدلائل الإرشادية للتبرع بالأدوية خلال الأعوام 2008-2000

تدوير الدواء. كانت تبرعات الأدوية المرتبطة بالكوارث في الأرجح هي الأقل التزاماً بالدلائل الإرشادية، ولاسيما من حيث تلبية متطلبات المتلقين للتبرعات، وضمان الجودة، وصلاحية عمر الأدوية لحفظها على الأرفف، والتعبئة، والتوسيم، وإدارة المعلومات. وقد عانت البلدان المتلقية للتبرعات من أعباء وتكاليف التخلص من الأدوية التي تلقتها نتيجة للتبرعات غير الملائمة. وبالرغم من أن التبرعات طويلة الأمد كانت في الأرجح تلتزم بالدلائل الإرشادية لمنظمة الصحة العالمية المتعلقة بضمان الجودة، والتوسيم، إلا أنها لم تراعي باستمرار تلبية احتياجات المتلقين للتبرعات. والأسوأ من ذلك أنها أثبتت العزم على الإنتاج والتطوير المحلي للأدوية.

الاستنتاج تبرعات الأدوية تصيب البلدان المتلقية لها بضرر أوخم من ما تجلبه من نفع. وسيؤدي تعزيز بنين ونظم التنسيق والرصد لتبرعات الأدوية وضمان تلبية هذه التبرعات لاحتياجات المتلقين لها إلى رفع مستوى الالتزام بالدلائل الإرشادية للتبرع بالأدوية التي وضعتها منظمة الصحة العالمية.

الغرض تقييم التبرع بالأدوية من حيث الالتزام بالدلائل الإرشادية لمنظمة الصحة العالمية للتبرع بالأدوية.

الطريقة في عام 2009، أجرى الباحثون بحثاً في النشريات الأكاديمية والنشريات غير الرسمية - من خلال المقالات المنشورة في المجلات، ووسائل الإعلام، ومواقع الإنترنت للمصانع والجهات المانحة - لتحديد التقارير عن تبرعات الأدوية خلال الفترة من عام 2000 حتى 2008. وقد استُبعدت النشريات التي ركزت على الآليات الجزئية لعمل الدواء، والصفات العامة للدلائل الإرشادية أو الخاصة بالتبرع بالدواء لمرة واحدة قبل عام 2000. وبالنسبة للحالات التي توافرت فيها معلومات كافية، قيم الباحثون الالتزام بحسب الاثنتي عشرة مادة في الدلائل الإرشادية لمنظمة الصحة العالمية.

الموجودات اكتشف الباحثون 95 مادة تصف 96 واقعة تبرع بالدواء خلال الفترة 2008-2000، منها 50 تبرعاً استجابة لحالات الكوارث، و 43 تبرعاً شمل تبرعات طويلة الأمد لمعالجة أمراض خاصة، وثلاثة تبرعات لحالات

Resumé

Mieux vaut donner que recevoir : conformité avec les directives de l'OMS en matière de dons de médicaments sur la période 2000-2008

Objectif Évaluer les dons de médicaments sous l'angle de leur respect aux directives sur les dons de médicaments de l'Organisation mondiale de la Santé (OMS).

Méthodes En 2009, nous avons effectué des recherches dans la documentation académique et autre (articles de journaux, articles de presse, sites Internet du secteur et des donateurs) afin d'identifier les rapports sur les dons de médicaments effectués entre 2000 et 2008. Nous avons exclu les publications axées sur les mécanismes moléculaires de l'action des médicaments, les descriptions générales des directives ou les anciens dons uniques de médicaments spécifiques antérieurs à 2000. Pour les cas comportant suffisamment d'informations, nous en avons évalué la conformité avec chacun des 12 articles des directives de l'OMS.

Résultats Nous avons trouvé 95 articles relatant 96 occurrences de dons de médicaments sur la période 2000-2008. Sur ces 96 occurrences, 50 ont eu lieu en réponse à des catastrophes, 43 impliquaient le don de médicaments à long terme visant à traiter une maladie spécifique et 3 étaient des cas de recyclage de médicaments. Les dons liés aux

catastrophes étaient les moins susceptibles de respecter les directives, notamment en ce qui concerne la réponse aux besoins du receveur, l'assurance qualité, la durée de conservation, l'emballage, l'étiquetage et la gestion de l'information. Les pays receveurs avaient à leur charge les frais relatifs à la destruction des médicaments reçus via des dons inappropriés. Même si les dons à long terme étaient certainement plus à même de respecter les directives de l'OMS en termes d'assurance qualité et d'étiquetage, ils ne répondaient pas de manière cohérente aux besoins des receveurs. En outre, ils entravaient le développement et la production de médicaments locaux.

Conclusion Les dons de médicaments peuvent faire plus de mal que de bien aux pays receveurs. Le renforcement des structures et des systèmes de coordination et de contrôle des dons de médicaments, ainsi que la garantie qu'ils sont guidés par les besoins des receveurs, permettront d'améliorer l'adhésion aux directives sur les dons de médicaments préconisées par l'OMS.

Resumen

Dar es mejor que recibir: cumplimiento de las directrices de la OMS sobre las donaciones de medicamentos entre 2000 y 2008

Objetivo Evaluar las donaciones de medicamentos en lo que respecta a su adhesión a las directrices sobre donación de medicamentos propuestas por la Organización Mundial de la Salud (OMS).

Métodos En 2009 se realizaron búsquedas bibliográficas de las publicaciones universitarias y legas (artículos de revistas, artículos en medios de comunicación, así como las páginas web del sector y de los donantes) para identificar los informes sobre donaciones de medicamentos realizadas desde el año 2000 hasta el 2008. Se excluyeron las publicaciones centradas en los mecanismos moleculares de la acción farmacológica, las descripciones generales de las directrices o las donaciones únicas y específicas de medicamentos anteriores al año 2000. En los casos en los que se contó con suficiente información, se evaluó el cumplimiento de cada uno de los 12 artículos de las directrices de la OMS.

Resultados Encontramos 95 artículos en los que se describían 96 casos de donaciones de medicamentos entre 2000 y 2008, de los cuales,

50 se realizaron en respuesta a situaciones de desastre, 43 estaban relacionados con la donación a largo plazo de un medicamento para tratar una enfermedad específica y 3 versaban sobre el reciclaje de fármacos. Las donaciones relacionadas con desastres fueron menos proclives a cumplir las directrices, en concreto por lo que respecta a satisfacer las necesidades de los destinatarios, la garantía de calidad y la fecha de caducidad, el envasado y el etiquetado, así como la gestión de la información. Los países receptores tuvieron que hacer frente a los costes de la eliminación de los medicamentos recibidos mediante donaciones inapropiadas. Aunque las donaciones a largo plazo fueron más propensas a cumplir las directrices de la OMS relacionadas con la garantía de calidad y el etiquetado, no siempre se ajustaron a las necesidades de los destinatarios. Por otra parte, frenaron la producción y el desarrollo farmacológicos a nivel local.

Conclusión Las donaciones de medicamentos pueden perjudicar más que beneficiar a los países receptores. La consolidación de las estructuras y los sistemas de coordinación y seguimiento de las donaciones de

medicamentos, así como la seguridad de que se realicen en función de las necesidades de los beneficiarios, mejorarán la adhesión a las directrices sobre la donación de medicamentos establecidas por la OMS.

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