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Introduction and Summary

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Introduction

In May 1996 the World Health Organization (WHO) issued its *Guidelines for Drug Donations*.[1] According to the document, the *Guidelines* were developed by WHO and reflected "a consensus between the major international agencies active in humanitarian emergency relief" (the eight organizations listed as co-authors on the document's cover). Furthermore, the document was issued not as an "international regulation" but rather "as a basis for national or international guidelines, to be reviewed, adapted and implemented by governments and organizations dealing with drug donations." The *Guidelines* were published "as an interagency document and will be reviewed after one year on the basis of comments received during their use." Throughout this report, we refer to the interagency document as the WHO *Guidelines*.

The WHO document identified six main problems associated with drug donations, and it proposed 12 guidelines intended to improve the "positive impacts" associated with drug donations. Previous studies provided evidence of various problems in pharmaceutical donations, especially in disaster-relief situations.[2–7] These reports have used various methods for assessing the appropriateness of donated drugs, and have focused more on practices during disaster-relief than on practices during development-aid situations.

The publication of the WHO *Guidelines* in May 1996 raised a number of concerns among private voluntary organizations (PVOs) and pharmaceutical firms in the United States. First, they were concerned that the WHO *Guidelines*, if implemented, would reduce the flow of pharmaceu-

tical donations and, as a consequence, would negatively affect the quality of health services and health status in recipient countries. Second, they were concerned that WHO and other sponsoring agencies for the *Guidelines*, in evaluating the *Guidelines* a year later, would not adequately consider the benefits of current donations or the potential negative consequences of implementing the *Guidelines*. Third, they were concerned that no independent assessment of drug donations, taking into account both benefits and problems, had been conducted. The current study was designed in response to a request for proposals issued by a group of US-based pharmaceutical companies and PVOs; an interdisciplinary team organized at the Harvard School of Public Health conducted it.

Our study is designed as an independent assessment of pharmaceutical donation processes and outcomes, with particular attention to the relevance, quality, policies, and logistics of donations. A major goal is to fill some of the information gaps that exist about drug donation processes and outcomes. The study has the following three objectives:

1. To describe and assess key aspects of pharmaceutical donation processes, including processes within donor firms, PVOs, and recipient organizations.

2. To describe and assess the kinds of benefits and problems associated with drug donations.

3. To propose recommendations for improving the positive impacts and diminishing the negative aspects associated with pharmaceutical donations, for use by the major actors involved.

Overall, the study demonstrated that the drug donation process is extremely complex, involving several layers of different kinds of organizations. Four of the main findings from our study are as follow:

1. Our analysis of drug classification showed that between 37 and 65 percent of unique drug products donated to our three study countries (Armenia, Tanzania, and Haiti) by two US PVOs over two to three years were listed on the national Essential Drug Lists (EDLs), and that between 50 and 80 percent were either on the national EDLs or were therapeutic alternatives for EDL drugs (see Chapter 2).

2. Our analysis of product dating found that nearly 75 percent of drug shipment items in our sample (donations sent by two US PVOs over two to three years) had remaining time to expiration of greater than

one year at the time of shipment by the PVO; the average time in storage for shipment items was 113 days (see Chapter 3).

3. Our analysis of donation policies showed that pharmaceutical companies and PVOs have a great variation in the content and quality of their donation policies, and that both donor firms and PVOs are making efforts to develop explicit donation policies (see Chapter 4).
4. Our field studies in recipient countries found that donations are perceived as important and as having a positive impact by recipients in health facilities, who also identified problems that exist in the drug donation process. Interviewees expressed support for the WHO *Guidelines*, as long as exceptions to the guidelines could be managed by national policymakers or by local health facilities (see Chapters 5, 6, and 7).

This introduction provides background on the WHO *Guidelines*, the methods of our study, the main results of the study, and a discussion of recommendations to improve drug donation processes.

Background on the WHO *Guidelines*

According to the WHO document, the first guidelines for drug donations were developed by the Christian Medical Commission (CMC) of the World Council of Churches. At a meeting of the Pharmaceutical Advisory Group of the CMC in April 1988, five main complaints with drug donations were reported.[8] According to the CMC, donations:

- arrived after or near expiration dates,
- were inappropriate or unsuitable for treating diseases in the recipient country,
- were sent without first asking the recipients about their needs,
- were sent to the recipients without prior notification or shipping documents, and/or
- were inadequately packaged or labeled, with no prescriber or patient information.

In response to these problems, the Christian Medical Commission developed six guidelines and presented them in the *Guidelines for Donors and Recipients of Pharmaceutical Donations*, which were published in

April 1988 (Table 1.1).[8] The CMC guidelines closely resemble a number of the criteria used in the WHO *Guidelines*.

The initial draft of the WHO *Guidelines* was prepared within the WHO Action Program on Essential Drugs and was then "refined" in collaboration with the WHO Division of Drug Management and Policies and the WHO Division of Emergency and Humanitarian Action.[1] The final text was developed by WHO with seven cosponsoring organizations: Office of the United Nations High Commissioner for Refugees, United Nations Children's Fund, International Committee of the Red Cross, International Federation of the Red Cross and Red Crescent Societies, Médecins sans Frontières, Churches' Action for Health of the World Council of Churches, and OXFAM. In addition, comments from over 100 humanitarian organizations and individual experts "were taken into consideration" in developing the *Guidelines*.

The WHO document states that drug donations occur through five "different scenarios": (1) acute emergencies, (2) development aid in nonemergency situations, (3) corporate donations (direct or through private voluntary organizations), (4) aid by governments, and (5) donations aimed directly at single health facilities. The document then asserts, "Although there are legitimate differences between these scenarios, there are many basic rules for an appropriate donation that apply to all. The guidelines aim to describe this common core of 'Good Donation Practice'."

TABLE 1.1

CMC Guidelines for Donors and Recipients of Pharmaceutical Donations

1. Donations should consist only of essential drugs included on national drugs lists, if existing, or otherwise appearing in the WHO model list of essential drugs.
2. Drugs should be labeled by the generic-international nonproprietary name (INN).
3. If a drug is sent to the same place or program regularly, preferably the strength of the drug should not change.
4. Packaging units containing larger quantities are more suitable than small packets. (This guideline should not be understood as an encouragement to repack from small packaging units of different batches and expiration dates.)
5. Drugs should have a shelf life of at least one year after estimated arrival in the country.
6. To enable local purchase, a financial contribution will, in many cases, be more appropriate.

Source: World Council of Churches, Christian Medical Commission, *Guidelines for Donors and Recipients of Pharmaceutical Donations* (Geneva: World Council of Churches, 1988).

In a section on "the need for guidelines," the WHO document mainly discusses problems in acute emergency relief aid. The six main problems (Table 1.2) appear to be based on the list developed by the CMC (see above). The WHO document does not provide background data on the frequency of problems that occur in drug donations, on the total volume of drug donations shipped to developing countries (the denominator for the frequency), on the benefits that result from drug donations, or on the relative importance of the different kinds of problems that occur. The document states, "Numerous examples of inappropriate drug donations have been reported," then provides an annex with eight examples, including one earthquake, three civil wars, two post-socialist transitions, and two cases of collecting unused patient drugs in Europe. The WHO document does not provide or cite an assessment of the overall situation of drug donations. The document primarily refers to single-incident reports of problems with drug donations, mostly in disaster-relief situations.

The WHO document identifies "four core principles" as the basis for the *Guidelines for Drug Donations:*

1. Maximum benefit to the recipient.
2. Respect for wishes and authority of the recipient.
3. No double standards in quality.
4. Effective communication between donor and recipient.

Based on these four principles, the WHO document provides 12 guidelines for drug donations (see Table 1.3). Each guideline is accompanied by a "justification and explanation" and by "possible exceptions."

TABLE 1.2

Six Problems Associated with Drug Donations

1. Donated drugs often are not relevant for the situation.
2. Many donated drugs arrive unsorted and labeled inappropriately.
3. The quality of donated drugs does not always comply with standards in the donor country (including expired drugs, drugs returned from patients, or free samples).
4. The donor agency sometimes ignores local administrative procedures.
5. Donated drugs having a high declared value, based on the market value in the donor country, lead to high customs charges for recipients.
6. Drugs may be donated in the wrong quantities, creating disposal problems.

Source: *Guidelines for Drug Donations* (World Health Organization, 1996).

TABLE 1.3

WHO *Guidelines for Drug Donations*

Selection of Drugs

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

Quality Assurance and Shelf-Life:

1. All donated drugs 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 should be used.
2. No drugs should be donated that were issued to patients and then returned to a pharmacy or elsewhere, or that were given to health professionals as free samples.
3. After arrival in the recipient country, all donated drugs should have a remaining shelf life of at least one year.

Presentation, Packing, and Labeling

1. All drugs should be labeled in a language that is easily understood by health professionals in the recipient country; the label on each container should contain at least the International Nonproprietary Name (INN, or generic name), batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions, and expiry date.
2. As much as possible, donated drugs should be presented in larger-quantity units and hospital packs.
3. All drug 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. Drugs should not be mixed with other supplies in the same carton.

Information and Management

1. Recipients should be informed of all drug donations that are being considered, prepared, or actually underway.
2. In the recipient country, the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in that country or, if such information is not available, on the wholesale world-market price for its generic equivalent.
3. 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: *Guidelines for Drug Donations* (World Health Organization, 1996).

The guidelines are divided into four categories (with three guidelines per category): (1) selection of drugs, (2) quality assurance and shelf life, (3) presentation, packing, and labeling, and (4) information and management. The document provides minimal explanation of the core principles or of how the individual guidelines were derived from the core principles. (Each core principle could be interpreted in various ways, with different implications for how the *Guidelines* are implemented.)

In response to the WHO *Guidelines*, a group of healthcare companies and PVOs in the United States began to meet to discuss their concerns about the *Guidelines* and pharmaceutical donations. From these discussions emerged the document titled, *Statement of Principles in the Provision and Distribution of Donated Medicines and Medical Supplies for Disaster and Humanitarian Relief*, which was available as "Working Draft No. 8" in July 1997.[9] The document is referred to as the PVO-Industry *Principles* in this report. A revised final version was released in April 1998.[10]

The PVO-Industry *Principles* were prepared by organizations "dedicated to augmenting the usefulness of medicines and related products donated by corporations and distributed by PVOs to serve the medically indigent around the world." The first sentence of the document states that the members of the joint PVO-Industry committee are "committed to ensuring the appropriateness and quality of medicines donated to aid communities around the world that are struck by disasters or hampered by economic distress." The *Principles* are presented not as formal regulations or as exhaustive norms but rather as "guidance to donors and PVOs in formulating their individual policies and procedures." The final document sets forth five principles for donor companies, six principles for PVOs, one principle for recipient countries, and one principle for administration. Like the WHO *Guidelines*, the PVO-Industry *Principles* does not provide background data on the patterns of drug donations. The statement made in a previous analysis of drug donations in 1990 still seems valid: "No systematic assessment of the impact of donated pharmaceuticals has been carried out."[11]

In this report, the WHO *Guidelines* were used to design the research questions in each component of this study (as described below). In addition, we used some criteria from the WHO *Guidelines* along with some from the PVO-Industry *Principles* as normative standards to assess the policy statements of donor companies and PVOs (as described below in the methods for the donation policy study). The full texts of the WHO *Guidelines* and the PVO-Industry *Principles* are provided in Appendices 1 and 2 of this report.

Methods

To assess pharmaceutical donation processes from different perspectives, a multidisciplinary team used qualitative and quantitative research methods in four substudies. The team collected data from government officials and health facilities in recipient countries, from PVOs and companies in the United States, and from the WHO. As shown in Table 1.4, the four study components used different sources of information and different kinds of analysis:

1. *Classification of donated drugs:* In this component, the study team designed a system for classifying donated drugs according to therapeutic category and status on national EDLs and the WHO Model List of Essential Drugs (WHO-ML) to examine the potential relevance of donated drugs to local disease patterns and pharmaceutical priorities.
2. *Quantitative study:* In this component, the study team created and analyzed a data base of all donated drugs received and shipped worldwide by two US PVOs over a two- to three-year period, with attention

TABLE 1.4
Study Components

Study Component	Donation Process Assessed	Source of Information
1. Classification study	Relevance	Two PVO data bases: Drugs shipped to three countries; national EDLs of three countries
2. Quantitative study	Quality	Two PVO data bases: Drugs shipped to a total of 129 countries
3. Donation policy study	Selection Quality Logistics	Company policies PVO policies
4. Field studies	Selection Quality Logistics	Interviews with: MOH Officials Health Care Providers NGO/PVO Officials

Abbreviations:
PVO = Private Voluntary Organization
NGO = Nongovernmental Organization
MOH = Ministry of Health
EDL = Essential Drugs List

to WHO-ML status and remaining shelf life, to examine some aspects of the quality of donated drugs.

3. *Donation policy study:* In this component, the study team collected and analyzed the donation policy statements of major US donors, including both pharmaceutical companies and PVOs, to analyze selection, quality, and some aspects of logistics.

4. *Field survey study:* In this component, the study team conducted interviews with practitioners and administrators at governmental and nongovernmental health facilities in three recipient countries to examine the processes of requesting and receiving donated drugs, from the recipients' perspectives.

The same data base was used for the classification study and the quantitative study. We obtained data on all products shipped worldwide by two US-based PVOs from 1994 to 1997. The PVOs were not selected randomly, but were suggested by the study's sponsors as PVOs that handle large quantities of donated drugs on a regular basis. The two PVOs asked to remain anonymous. According to a list of PVOs registered with the US Agency for International Development,[12] the two study PVOs ranked among the top 10 out of 54 PVOs stated as working with pharmaceuticals or medical supplies (when ranked according to the amount of in-kind contribution, ranging from $23–138 million in the top 10), and representing 16 percent of the total value of in-kind contributions for all 54 PVOs in 1995 (total of about $830 million, including pharmaceutical as well as other in-kind contributions). These data are the best figures available to the public on PVO pharmaceutical donations in the US, and indicate that the two selected PVOs in this study are major organizations in this field.

Each study component is briefly described below, with the main questions for analysis, the methods of analysis, and the limitations of each study.

Classification of donated drugs

We developed a classification system based on EDL status,[13,14] as contained in Guideline No. 2 of the WHO document, to assess the relevance of donated drugs. Guideline No. 2 states, "All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO Model List of Essential Drugs, unless specifically requested otherwise by the recipient." National EDLs, which are modeled

after the WHO-ML, include drugs that are considered appropriate for the local disease patterns and circumstances of care. We used the 1995 version of the WHO-ML, which includes the provision of "therapeutic alternatives" for 108 drugs that represent a therapeutic class (allowing an alternative drug to be substituted from the same pharmacologic class). The remainder (196 drugs) are not subject to acceptable substitution.[13] We applied the WHO-ML provision for therapeutic alternatives to the three national EDLs (which were obtained in the field studies and do not allow for substitution by therapeutic class). Two clinical pharmacists, Anita Wagner and Frank Massaro conducted the study.

The classification system included four categories: (1) drugs that appear on the country's EDL, (2) drugs that are in a therapeutic group of the national EDL and are a permissible therapeutic alternative according to the WHO-ML, (3) drugs that are not in the first two categories but are on the WHO-ML, and (4) drugs that are not in any of the three previous categories and called non-list drugs. We applied this classification to a data base of drugs donated by two US PVOs to the field study countries (Armenia, Tanzania, and Haiti). This data set was a subset of the study's PVO data base (described below in the quantitative study).

For our analysis of potential relevance, we defined a "unique drug product" as *a particular drug, in a particular dosage form and strength* (without regard to package size). We compared each unique drug product with the national EDL and with the WHO-ML. A unique drug product was classified as on the country EDL or WHO-ML if the drug in the same dosage form was listed for the same indication (without regard to strength). Each unique drug product was counted once, even if the same product was shipped multiple times.

Quantitative study

In this component, the study team analyzed data on donated drugs obtained from two US PVOs. The data included all products shipped by the two PVOs to countries outside the United States from 1994 to 1997. This analysis sought to describe major patterns in our sample of drug donations and to assess potential impacts of implementing the WHO *Guidelines*, with particular attention to the criteria on shelf life (time to expiration) and WHO-ML status. All raw data and data sources are strictly confidential. The quantitative study was carried out by Thomas McLaughlin and Xiaoming Gao, health services researchers and statisticians at Harvard Medical School.

For the quantitative analysis, we defined a "shipment item" as *one donated drug product in a particular dosage form, strength, and package size that was listed on the PVO's shipment list as a line item*. Multiple shipment items existed of the same drug product, and each shipment item was counted separately. A "shipment" was defined as *all the shipment items sent by a PVO on the same date*. The PVO data set included data for approximately two and a half years for PVO A (January 1994 to May 1996) and three years of data for PVO B (July 1994 through June 1997). We obtained data on 11,321 shipment items from PVO A to 117 recipient countries, in a total of 1,017 shipments during the study period, and data on 5,245 shipment items from PVO B to 67 recipient countries, in a total of 1,597 shipments during its study period.

Five types of analysis were conducted. First was an analysis of time to expiration (remaining shelf life) for donated drugs at the time of shipment by the PVO. Next was an assessment of drug donations according to EDL status, using the WHO-ML. Third was a descriptive analysis of the distribution of shipments across therapeutic categories. Fourth was a descriptive analysis of the distribution of recipient countries, according to the frequency of donation shipments. The final assessment used regression analysis to determine whether the introduction of the WHO *Guidelines* had an effect on the median time to expiration for donated drugs. These analyses are the first systematic examination of patterns in pharmaceutical donations using data obtained from PVOs.

This analysis has several limitations. First, the quantity of donated drugs (in terms of unit doses or weight) was not measured or estimated; instead, the frequency of shipments of any individual drug (a shipment item) was used as a proxy for quantity. Therefore, conclusions involving the quantity of donated drugs cannot be drawn. Second, the study may be biased in a positive direction if the two selected PVOs are particularly concerned with the appropriateness and quality of donated drugs. And third, the study assessed only two dimensions of the WHO *Guidelines*, those related to essential-drugs status and to expiration dates.

Donation policy study

In this component, the study team sent a letter to 36 pharmaceutical companies and 31 PVOs, requesting a copy of the organization's policies on pharmaceutical donations. The policy statements were evaluated for content using two normative standards: criteria from the WHO *Guidelines* and criteria from the PVO-Industry *Principles*. The policy statements were then assessed from a textual perspective for the quality of

explication, transparency, and completeness. Follow-up telephone interviews were conducted with respondents from PVOs and pharmaceutical companies to clarify some aspects of the policy statements and to collect additional information. The names of all individuals and organizations are strictly confidential. Lisa Bates, a health policy analyst, carried out the donation policy study.

One limitation of this study is that the sample of companies and PVOs may not be representative of the broader set of organizations involved in pharmaceutical donations. The results could be biased in a positive direction, since organizations with explicit policies may be more likely to respond. Some organizations, indeed, refused to provide us with their policy statements, which they considered proprietary and confidential; others revised (or wrote) policy statements on drug donations in response to our request.

Another limitation is that the study did not examine the connection between policy statement and organizational behavior. An organization may have an excellent policy statement but not implement the policy, so that performance does not comply with the policy. Conversely, an organization may have a poor-quality policy statement (or no written policy) but have informal practices that comply with the major criteria of the WHO *Guidelines* or the PVO-Industry *Principles*. Inferences about drug donation practices, therefore, cannot be drawn directly from this assessment of policy statements.

Despite these limitations, this study is the first systematic analysis of PVO and company policies on drug donations. From this perspective, we hope that its findings will help inform a broader discussion about the content and the use of drug donation policies.

Field survey study

This component provides a qualitative analysis of the experiences with donated drugs in three countries (Armenia, Tanzania, and Haiti), based on interview data and direct observation, to assess the processes and some of the perceived impacts of US pharmaceutical donations on health services in recipient countries. The field surveys also collected interview data on the potential impacts of implementing the WHO *Guidelines* under various conditions. The three countries for the field survey were selected, in consultation with the sponsors group, to include countries involved in pharmaceutical donations in nonemergency situations and countries receiving significant contributions from US PVOs. In this component, the study team used the same structure for data collection in

the three countries and asked a set of basic questions in interviews conducted at the ministry of health in each country, the government pharmaceutical warehouse, governmental and nongovernmental health facilities (both urban and rural, and hospitals and clinics), and PVOs in the country. As part of this study, we agreed to keep confidential the names of all organizations and individuals. The field surveys in Armenia and Tanzania were carried out by Karin Dumbaugh, and the survey in Haiti was conducted by Michèle Derai-Cochin; both researchers have extensive experience in qualitative interview methods and health services research.

The field studies have the normal limitations associated with case studies. The cases cannot represent the overall situation of pharmaceutical donations and may not reflect the scale of problems that occur in emergency relief situations. Time and budget limitations restricted the number of interviews conducted and the distribution of facilities visited in each country. In Armenia, an interpreter was used for all interviews, which may have limited the information collected. Finally, the quantitative data were collected in interviews and were not validated independently, while the qualitative data may reflect some biases of the respondents.

The field surveys represent the first systematic effort to investigate experiences with drug donations across several developing countries. The reports of the three field surveys use a similar format, as shown in Table 1.5 (with some minor variations in the structure of the three chapters). For each country, we provide an overview of the drug donation process in that country, a description of the government's role in drug donations, and information on the sources of donated drugs, the characteristics of donated drugs, the main ways that groups receive donated drugs in that country, and the main benefits and drawbacks of donated drugs in that country, as reported by the interviewees. Each country report includes respondents' views on the WHO *Guidelines* and recommendations for the improvement of drug donation processes in the country. A summary of each country report is provided in Appendices 4 (Armenia), 5 (Tanzania), and 6 (Haiti).

Main Results

Classification of donated drugs

Our analysis of drugs in the PVO data base that were donated to the three study countries (Armenia, Tanzania, and Haiti) showed that between 37 and 65 percent of unique drug products were listed on the country's

TABLE 1.5

Outline of Field Survey Reports for Armenia, Tanzania, and Haiti

Executive Summary
- Purpose, data sources, and methods
- Results
- Recommendations

Introduction
- Background on the country
- Limitations of the field study

Profile of the Interviewees
- The health facilities
- The in-country PVOs
- The Ministry of Health

Description of the Current Donation Process
- Regulations on drug donations: Role of the Ministry of Health
- Sources of drug donations, actors involved, and logistics of the shipments
- Characteristics of the donated drugs

Perceptions of the Current Drug Donation Process by the Recipients
- Regulations on drug donations
- Benefits and drawbacks of the current drug donation process

WHO *Guidelines For Drug Donations*
- Knowledge of and reactions to the WHO *Guidelines*
- Potential impacts of the WHO *Guidelines*
- Other aspects of donation policies that require improvement

Conclusions and Recommendations
- Strengths and weaknesses of the current drug donation process
- Reactions to the WHO *Guidelines* and potential impacts
- Recommendations for improving the drug donation process in the country

EDL, and between 50 and 80 percent were either on the country's EDL or were permissible therapeutic alternatives according to our application of the WHO-ML provisions to the three country EDLs (see Table 2.1). Of the remaining products, between 1 and 15 percent appeared on the WHO-ML (1995 version), and between 10 and 42 percent were non-list drugs that did not belong to any of the three categories.

Quantitative study

The study produced the following observations about the flow of donated drugs in the two PVOs:

Time before expiration: The median remaining time before expiration at the time of shipment by the PVO was 599 days for PVO A and 550 days for PVO B for all worldwide shipment items (see Figures 3.1 and 3.2). We did not observe any systematic or significant differences in these values when stratified according to status on the WHO-ML. About 30 percent of the shipment items had one year or less of shelf life remaining at the time of shipment, and 5.6 percent of all shipment items for both PVOs had less than 100 days of shelf life at the time of PVO shipment.

WHO-ML and country EDL status: For the full PVO data base, 14.9 percent of PVO A's shipment items and 26.1 percent of PVO B's shipment items were on the WHO-ML. The proportion of shipment items with EDL status can be significantly higher when analyzed on a country-by-country basis. For example, analysis of donations to Armenia showed that nearly 75 percent of all shipment items from PVO A and 66 percent of those from PVO B appeared on the Armenian EDL.

Therapeutic category mix: The most frequently shipped items were drugs in the following therapeutic categories: anti-infectives, analgesics, cold preparations, and anti-inflammatory agents.

Recipient countries: The countries that most frequently received drug donations were: for PVO A, El Salvador, Honduras, Nicaragua, Romania, Russia, and the Ukraine; and for PVO B, Croatia, El Salvador, Honduras, Lithuania, Peru, and the Ukraine.

Effects of the Guidelines: Time-series analysis with data from one PVO (with regression modeling of the time before expiration, at the point of shipment by the PVO) was unable to detect any significant changes in shelf-life duration following the introduction of the WHO *Guidelines* in May 1996. The potential for "anticipatory" responses was also considered by performing the analysis with the date of introduction of the *Guidelines* moved to January 1996; again, no effect was detected.

Data management: The study identified two problems for external use of the PVO data: First, the two PVOs in our sample used a variety of data-management methods, without consistency or uniformity over time; and second, PVOs recorded their drug donations according to various data elements.

Donation policy study

A wide diversity in the quality and content of drug donation policies was found for our sample of companies and PVOs. We received responses from 18 of 36 pharmaceutical companies and from 13 of 31 PVOs, yielding a combined response rate of 46.3 percent.

Written policy: For companies, 10 of the 18 respondents provided the firm's donation policy. Five companies that responded did not have a written donation policy; three companies refused to provide policy statements for confidentiality and other reasons. For PVOs, 11 of 13 respondents provided a written donation policy. This finding for PVOs represents a significant improvement over a small survey conducted in 1989–1990 that found only two of eight PVOs reported having written policies on drug donations.[11]

Selection: None of the companies' and only two of the PVOs' written policies included statements pertaining to the status of donated drugs on the WHO-ML or national EDLs. A number of PVOs, however, reported in follow-up interviews that they use EDL status in selecting pharmaceutical donations for specific countries.

Expiration: The survey found that only 2 of 11 of the PVOs' policies are consistent with the 12 months minimum shelf life (on arrival in the recipient country) called for by the WHO *Guidelines.* Only one company's policy agreed with the WHO standard of 12 months minimum shelf life, but the majority of both corporate and PVO policies agreed with the 6 months minimum proposed in the July 1997 PVO-Industry *Principles.* (The final version of the *Principles*, released in April 1998, proposes a 12-month minimum for arrival at the PVO.)[10]

Type of donation: In our sample, the most common type of donation program is inventory management; nine companies include inventory management as a major factor in the donation policy. Only four companies explicitly mention production-for-donation in their policy statements.

Communication: Most PVOs have introduced various mechanisms to screen recipients, communicate about specific donation shipments, and document end-use, reflecting efforts to communicate with recipients. Ongoing communication between donors and recipients is important for the processes of selecting recipients, determining product needs and availability, and assuring donation follow-up. The survey found that most companies manage these communication processes by working with a limited number of PVO partners on a continued basis.

Transparency: No PVOs or companies in our sample included an explicit statement on the public availability of the organization's donation policy. The study found a relatively low level of transparency and relatively little communication across organizations about donation policy.

Field survey study

The field surveys conducted in Armenia, Tanzania, and Haiti in summer 1997, yielded a wealth of information on actual experiences with donated drugs, including qualitative observations at health facilities, as well as opinion data on the WHO *Guidelines*. The main results are as follow.

First, respondents in health facilities in all three countries appreciated the benefits of drug donations for a variety of reasons: the additional supply of products listed on national EDLs, the supply of products not listed on the national EDL, expanded financial flexibility through low-cost products, and expanded access to drugs for poor patients. The respondents perceived the benefits of donated drugs as real, multiple, and desired.

Second, the field surveys demonstrated the complexity of the drug donation process and its variations from country to country. The drug donation process is a complex system of organizations linking private companies, government bureaucracies, nongovernmental organizations, and international agencies. The study shows that various problems can arise among organizations, including problems in communication, standards, monitoring, and logistics. Many respondents did not fully understand the roles of other organizations involved in drug donations.

Third, these problems in organizational relations have consequences for the recipients of drug donations. Donations are not cost-free for recipients in health facilities, although the monetary and time costs vary by facility, source, and country. Shipments do not always match the needs or requests of recipients; health facilities may have to pay import duties and/or in-country transportation costs; and recipients have varying capacities to cope with these consequences and to increase the "yield" from donations. To increase the yield, recipients use such strategies as barter, dispensing expired drugs, sales to patients, and donations to other facilities.

Fourth, many recipients in health facilities expressed support for the intent of the WHO *Guidelines*, because the recipients were aware of problems in the drug donation process and would like to see it improved. In addition, the *Guidelines* were perceived as helping to empower the health facilities by changing the donor/recipient relationship. Many interviewees, however, had not seen or heard of the WHO *Guidelines* prior to our study.

Some respondents were concerned that the WHO *Guidelines* could have the unintended consequence of reducing the benefits associated with drug donations. Some respondents were concerned that the *Guidelines* could enhance the power of the government to control the flow of drug donations and thereby reduce the capacity of health facilities to solicit donations. They urged that the requests of the health facilities be protected and given priority as the recipient, rather than viewing the government as the sole legitimate recipient.

Discussion

This study shows that the processes of drug donations involve multiple organizations linked in a complex system. The study suggests that a large proportion of donated drugs meet certain indicators of relevance and quality. On the other hand, the study identifies problems with both relevance and quality, as expressed by the presence of category 4 drugs (non-list drugs) and by drugs shipped with shelf life under one year. Overall, the study identifies important benefits of drug donations, as well as areas for improvement, from the perspective of the recipients.

With regard to relevance, the study's classification system of donated drugs shows that a significant proportion (from 50 to 80 percent) of donated drugs for three countries in the study's PVO data base were either on the country's EDL or were therapeutic alternatives for the country's EDL drugs. The proportion is even higher (from 58 to 90 percent) if drugs on the WHO-ML are included. If these categories are used to define the "relevance" of donations to local disease patterns and national pharmaceutical priorities, then these results suggest that the majority of drugs selected for donation in this sample were relevant.

One important indicator of quality for drug donations is time to expiration. The study's analysis found that more than half of the shipment items in the PVO data base had more than 500 days before expiration at the time of shipment. If shipment to the recipient country takes one month, then these items would arrive well within the WHO *Guidelines*' standard of one year on arrival in the country. The results from the time-series analysis of data from one PVO suggest that the relatively long median shelf life was not associated with the introduction of the WHO *Guidelines*.

The study also shows the potential for problems with relevance and quality. Between 20 and 50 percent of the unique drug products selected for donation were not on the country's EDL and were not therapeutic

alternatives. We were unable to determine whether these products were requested by the recipient, which would make the products "relevant" according to Guideline No. 2. About 30 percent of the shipment items had less than one year of shelf life remaining at the time of shipment by the PVO. These items would not meet the standard in Guideline No. 6 of one year of shelf life on arrival in the recipient country.

The three field studies similarly identify both benefits and problems associated with pharmaceutical donations. The field studies show that recipients appreciate drug donations as a useful resource. Recipients use drug donations in multiple ways, depending on the specific context; at the same time, they expressed concern about multiple problems in the drug donation process, especially the lack of match between the supply from donors and the perceived needs of recipients.

This study suggests that the problems of drug donations may be more serious in disaster-relief situations than in ongoing development aid (or may be improving over time). For example, we found that 46 and 65 percent of the unique drug products shipped to Armenia by the two PVOs were listed on the Armenian EDL and were considered relevant. A study of the Armenian earthquake of 1988 found that only 42 percent of the donated drugs were considered relevant for the emergency situation.[3] According to the results of our field study in Armenia (Chapter 5), introduction of a national EDL and national drug donation policy, along with a central agency to review and approve donations, plus efforts by PVOs to abide by the Armenian policy on drug donations, all contributed to better performance under development-aid conditions.

We conducted a Medline search from 1959 to 1998 for key words associated with pharmaceutical donations (including developing countries, drug industry, drug storage, international cooperation, pharmaceutical preparations, relief work, and World Health Organization) and examined the bibliographies of articles published on drug donations. The search identified two journal articles that analyzed a large sample of drug donations: one for an earthquake[3] and one for a war.[7] The other publications were eight letters on specific incidents or countries,[4,5,15–20] two news articles on two countries,[6,21] and five articles on WHO policy or humanitarian agency policy.[22–26] It is difficult to compare the results of our study with these published reports, because the methods used to assess "appropriateness" are not similar or were not clearly defined in previous studies. The methods used in our study for evaluating relevance and quality could provide the basis for a standard procedure for assessing the appropriateness of donated drugs.

Our study raises a number of broader policy questions. A central issue is the role of the national EDL in decisions about drug donations. Guideline No. 2 recommends that drug donations be restricted to drugs on the national EDL unless a national list is not available (in which case the WHO Model List should be used), or "unless specifically requested by the recipient." The structure of this guideline prompts three questions.

First, should a national EDL, which is intended at least in part to guide cost-effective procurement decisions, be used as an exclusive list for product donations? In countries with limited prescribing information and limited prescriber expertise, this usage could be justified. But in countries with good availability of information and expertise, allowing therapeutic alternatives and non-EDL drugs would seem reasonable. If donations are restricted to EDL drugs, then poor patients and patients with unusual medical problems could lack access to non-EDL drugs that might include more specialized therapies and more expensive and potentially more effective drugs.

Second, who is the legitimate "recipient" of drug donations? The government and a non-governmental agency may disagree over the appropriateness of a specific drug as a donation, due to different views about non-EDL drugs, therapeutic substitutes, or time before expiration. The WHO *Guidelines* does not clearly define the "recipient." A broad definition of "recipient," which includes non-governmental organizations (NGOs), could expand the potential benefits of drug donations, especially in situations where the government is unstable or disputed and where NGOs operate responsibly.

Third, how should tensions between health policy and industrial policy be resolved? Restricting donations to EDL drugs could have unintended negative consequences from an industrial policy perspective. Donations of EDL drugs could undermine retail sales of those products and could adversely affect local pharmaceutical production, which often begins with the generic products on a national EDL. Similar unintended market consequences have, indeed, occurred from donations of food aid.[27]

Several limitations of the study deserve attention. First, we did not measure or estimate the quantity of donated drugs (in terms of unit doses or weight). Instead, the frequency of shipments of any individual drug (a shipment item) was used as a proxy for quantity. Consequently, conclusions involving the quantity of donated drugs cannot be made. In addition, the results might change substantially if the observations were weighted by quantity. Additional research could be conducted to estimate overall flows of drug donations through PVOs based in the United

States and to provide some measures of quantity for specific indicators. Because we did not assess quantity, we cannot exclude the possibility of drug dumping. While the percentage of shipment items with less than 100 days to expiration was small, one or more of these shipment items could include a large quantity of short-dated products.

Second, the study focused on four dimensions of donated drugs (and a limited number of indicators): relevance (essential-drugs status), quality (shelf life), donation policies, and logistics. However, the appropriateness of donated drugs is decided on the basis of multiple criteria beyond these dimensions (including storage conditions, supply continuity, cost, the availability of alternative products, and the needs of particular patients). A definition of "appropriate" donations also depends on value judgments, including who decides on the criteria for drug donations, which products (and which patients) are given priority, whether the process is more supply-driven or demand-driven, and the balance between health and industrial objectives. We have not attempted to create a composite indicator of "appropriateness" for drug donations.

Third, we could not determine whether this two-PVO sample is representative of the overall flow of US drug donations, although these two PVOs are major organizations in this field. As noted above, the sample may have been biased in a positive direction if these two PVOs are particularly concerned with the appropriateness and quality of donated drugs. Also, we have not sought to compare the quality of drug donations from the United States with those from countries in Europe. Such a comparison could represent another area of future research with important policy implications.

Fourth, no attempt was made to validate the quantitative estimates and qualitative assessments provided in the field study interviews.

We would like to address directly the issue of sponsorship of this study by a group of pharmaceutical companies and private voluntary organizations, because such sponsorship could be cited as biasing the study's results or processes.[28] The sponsors group affected the study in three ways. First, we selected the three countries for field studies of nondisaster circumstances in consultation with the sponsors to represent different geographic regions, countries where US products have been received, and countries where US PVOs have been working. We do not think this selection significantly biased the results in a particular direction. Second, the sponsors assisted in identifying the PVOs that agreed to provide data for the study. This selection may have biased the study in a positive direction if those PVOs are more concerned about the relevance and

quality of donated drugs than others. Third, the full study was reviewed for comments not only by members of the sponsors group but also by WHO officials, critics of drug donations, and academics. We responded to all comments with equal attention, and the sponsors did not exercise any editorial rights over the manuscript. In short, the sponsors agreed to an independent study of drug donations as a precondition to the research.

Through this study, we identified four main areas of efforts needed to improve the positive impacts of drug donations.

1. For drug selection, we recommend that efforts be made to improve the match between the drug supply of donations (from donors and PVOs) and the drug demand for donations (by recipients). The four categories for classifying drug donations could assist the various organizations in the donation process in setting selection priorities for drug donations and in exploring how health facilities can use donated drugs more effectively.

2. For time to expiry, we recommend that efforts be made to improve the length of remaining shelf life by all groups involved in drug donations. The number of shipment items with shelf life under one year should be reduced, and short-dated drugs should be shipped only after prior acceptance by recipients and careful logistic attention, to assure that they are used prior to the date of expiration.

3. For donation policies, we recommend that efforts be made to develop performance standards on "best practices" for pharmaceutical donations and to develop policies for drug donations, for all organizations involved. The performance standards and the policy statements should be made available to end-use recipients.

4. For logistics, we recommend that efforts be made to improve two-way communication among donor companies, PVOs, recipient governments, and recipient health facilities. Better communication could help improve the match between the supply of donations and the perceived needs of the recipients. PVOs could also improve their methods for data-management of drug donations and the information systems for tracking donated products, in order to improve monitoring of the selection and quality of PVO drug donations.

Table 1.6 provides specific recommendations for all the actors (companies, PVOs, recipient governments, recipient health facilities, and WHO) on actions that could improve the positive impacts of drug donations.

TABLE 1.6

Recommendations

The study team proposes the following recommendations as actions that could improve processes and outcomes of pharmaceutical donations. The recommendations are organized by actor (companies, PVOs, recipient governments, recipient health facilities, and WHO), to indicate that each organization involved in the drug donation process can and should contribute to improvement. The order of the categories of organizations, and the order of the actions within each category, are not intended to represent priority. The recommendations are based on the study's analyses that demonstrated areas for improvement in drug selection, quality, donation policies, and logistics.

Companies:

- Provide a written and publicly available donation policy for each company.
- Do not donate drugs that are near the expiration date, and donate short-dated products on case-by-case decision only after communication with PVOs and/or recipients ascertaining that the recipient will receive and can use the short-dated products prior to expiration.
- Develop industry-wide standards for donation policies and for donation responsibility, in collaboration with PVOs.
- Increase production-for-donation, to assure that donated products have maximal time to expiration on arrival in the health facility and to assure continuity in the supply of constant types, dosage forms, and strengths of donated drugs.
- Support the development of PVO performance standards.
- Develop and implement procedures for regular communication with end-use recipients, in order to understand their perceptions of drug donations.
- Provide package inserts and product information for donated products.

PVOs:

- Provide a written and publicly available donation policy for each PVO.
- Minimize the time that a donation is held within a PVO warehouse, in order to assure maximum time to expiration for the health-facility recipient.
- Develop and implement procedures for regular two-way communication with end-use recipients, in order to match product availability and recipient requests.
- Develop PVO performance standards, in collaboration with companies and WHO.
- Develop improved data management capabilities, including the use of National Drug Classification (NDC) codes, which will facilitate the development of systems for product tracking, valuing, ascertaining the EDL status of drugs by country, and reporting.

Recipients (governments):

- Design a national policy for drug donations, in collaboration with WHO and with interested parties.
- Make the national drug donation policies and procedures available to PVOs, companies, and health facilities.
- Involve donor companies and PVOs in dealing with expiration date problems.
- Involve health facilities in decisions about drug donation policies.
- Provide training to health facilities on methods to improve the request and management of drug donations.

TABLE 1.6

Recommendations (continued)

Recipients (health facilities):
• Create and distribute a list of "always needed drugs" for the health facility to send to MOH, PVOs, and other interested parties.
• Establish mechanisms to communicate regularly with PVOs on the needs and uses of donated drugs.
• Establish systems to assess and predict health facility needs and to manage drug donations once received, including stock control systems using the First-Expiry-First-Out (FEFO) system.
• Train healthcare workers how to request donated drugs and how to decide on the request and use of donated drugs not listed on the country's EDL.
WHO:
• Clarify the role of exceptions for each guideline and how they should be implemented.
• Clarify the implications of who regulates drug donations within the recipient country.
• Monitor and publish national policies on tax and import duty exemptions for donations by recipient countries.
• Explain how potential conflicts between industry principles and WHO *Guidelines* can be addressed and resolved.
• Explain how to adapt the *Guidelines* to national conditions.
• Provide instructions to countries on the use of the *Guidelines* to improve the overall quality of drug donations.
• Provide a clearinghouse (worldwide web-based) for national EDLs and donation guidelines.
• Provide for independent and regular evaluation of WHO *Guidelines*.

In conclusion, this study shows that pharmaceutical donations are perceived as playing an important role in the healthcare systems of recipient countries, although the specific roles vary from country to country. Publication of the WHO *Guidelines* has raised international and national attention about the processes and the problems of drug donations. This study suggests a number of actions that could be taken to help improve the processes of drug donations and thereby enhance the positive impacts while reducing the negative and unintended consequences.

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