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## Field Study: Armenia

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### Introduction

The purpose of this study was to describe the process of drug donations in Armenia and, based on qualitative and quantitative assessments, to provide preliminary findings on the uses of US private drug donations in Armenia. The findings contained within the study are based upon interviews conducted during a seven-day trip to Armenia in May 1997. This first section (the Introduction) provides background information on Armenia and describes factors influencing the donation process in Armenia. It also discusses the limitations of the study. The second section provides information about the study period and the profile of the interviewees. The current donation process is described in the third section, and the recipients' perceptions of the process are discussed in the fourth section. Knowledge of and potential future impacts of the WHO *Guidelines* are described in the fifth section, and conclusions and recommendations can be found in the last section.

### Background on Armenia

The Republic of Armenia had a population of 3.8 million in 1996,<sup>1</sup> of which approximately 68 percent lived in urban areas, and 32 percent in rural areas.<sup>2</sup> Yerevan, the capital, accounted for one-third of the population, with 1.25 million people. This mountainous country of 30,000 square kilometers is located between Turkey to the west, Georgia to the north, Azerbaijan to the southwest and east, and Iran to the south.<sup>3</sup> Before the dissolution of the Soviet Union, Armenia's scenic beauty, historical sites, culture, and superior accommodations attracted many of

the USSR's top bureaucrats. Armenia's service industries, manufacturing plants, and agriculture were managed by a well-trained labor pool with a high literacy rate.

### ***Important factors affecting drug donations***

In the opinion of the informants contacted during the course of this study, four factors have affected and continue to influence the process of drug donations in Armenia:

1. The negative Armenian experience with donated drugs following the 1988 earthquake prompted the regulation and centralization of its drug donation process.
2. The dissolution of the Soviet Union and the subsequent collapse of the Armenian economy increased the need for drug donations during the 1990s.
3. The support of the Armenian Diaspora facilitates the supply of donations.
4. The ready availability of well-trained professionals increases the ability of Armenian health facilities to use many different drugs and to manage the complex logistics of donations.

### ***The Armenian earthquake***

In 1988 Armenia experienced a devastating earthquake that killed in excess of 25,000 people and virtually destroyed an entire region of the country. In the international humanitarian aid were large quantities of drugs, the majority of which were considered by the minister of health as either inappropriate or expired.<sup>4</sup> According to the former minister of health, the destruction of unusable donated drugs after the earthquake posed serious problems for the country. These problems, in turn, provided the incentive to develop a national drug policy and to establish a department to coordinate humanitarian aid, the Office for Humanitarian Assistance in the Ministry of Health.

### ***The collapse of the Soviet Union***

Prior to the collapse of the Soviet Union, the Armenian economy was controlled and coordinated with the other Soviet republics as part of the USSR. Armenia's healthcare system, and its drug supplies, were centrally managed by the USSR and were dependent upon the distribution mechanisms maintained by the Soviet economy. With the dissolution of the Soviet Union, Armenia's economy collapsed with the USSR's. The coun-

try is currently dependent on humanitarian assistance for drugs because it lacks sufficient funds to satisfy the need for drugs to provide healthcare services. The economic impact of the breakup of the Soviet Union and Armenia's geographic location make importing and exporting of raw materials and products costly, thus slowing the growth of the new Armenian market economy.

Armenia's economic problems have been exacerbated by the recent conflict with Azerbaijan over Nagorno-Karabakh, a region contained within the borders of Azerbaijan but predominantly settled by Armenians. This conflict led to a trade and transport embargo of Armenia by Azerbaijan and its allies, creating shortages of fuel oil, water, and electricity. Armenia's standard of living has declined since independence from the Soviet Union, and the 1995 per capita GNP was estimated at \$730 per year, including humanitarian assistance.<sup>5</sup>

### *The support of the Armenian diaspora*

The Republic of Armenia receives substantial support from its Armenian Diaspora, the roughly 5 million Armenians living in the United States, Europe, the Near East, Northern Africa, and Asia. Donations of drugs and medical supplies, healthcare training, and professional fellowships are important aspects of this support.

US donations are typically organized by US PVOs<sup>6</sup> that collect drugs and supplies. These donations are often collaborative with Diaspora PVOs<sup>7</sup> that solicit funds for transportation. The Armenian Diaspora and Diaspora PVOs also provide additional financial and other resources for Armenia. For example, a prominent American-Armenian donor underwrote a monthly cargo flight from the United States to Armenia for all of 1997.

Individual initiatives by US medical professionals of Armenian origin, such as the group of eye surgeons who perform surgery and conduct training sessions biannually at the national eye hospital, are of comparatively smaller scale. Nevertheless they play an important role in improving medical care in the country. These professionals also frequently obtain small quantities of pharmaceutical donations from their own US pharmaceutical suppliers and, thus, contribute to the supply of more specialized drugs in the country.

### *Supply of trained professionals in Armenia*

Armenia has no shortage of trained professional staff, including pharmacists, physicians, and nurses (see Table 5.1). According to those interviewed for this study, having this well-trained staff increases the ability to make use of drug donations that contain unfamiliar drugs without nega-

TABLE 5.1

**Availability of Medical Professionals and Immunization Services**

	Physicians/ 1,000 People (1988–1992)	Nurse-to- Doctor Ratio, (1988–1990)	Hospital Beds/1,000 People (1985–1990)	% Children <1year Immunized	
				DPT 3rd Dose (1990–1991)	Measles (1990–1991)
Armenia	4.28	2.5	9.0	88.0	92.0
Tanzania	0.03	7.3	1.1	79.0	75.0
United States	2.38	2.8	5.3	67.0	80.0

Source: The World Bank: *World Development Report 1995* (New York, 1995), pp. 184–222.

tively affecting the treatment. The country's literacy rate approaches 100 percent, and Armenia manages to educate the majority of its professionals. Many of the interviewed professionals, moreover, have also received training in Western Europe and America. The larger hospitals are able to access the Internet, and one hospital in our sample is linked via a Telemedicine program to a US hospital. The geographic isolation of the country has not cut off communication between Armenian professionals and their colleagues in other countries. Exchanges of professional visits are common, and each of the four teaching institutions interviewed had an overseas hospital "Partner." Institutions in the United States, Canada, or Europe provide professional assistance and occasionally solicit drugs and medical supplies for Armenian health facilities.

The Armenian medical and pharmaceutical professionals who were interviewed indicated that they are familiar with brand names of US, European, and Eastern European drugs and know how to use many of them. The hospitals in the study also had recent copies of the *Physicians' Desk Reference* (PDR).<sup>8</sup> The interviewed pharmacists said that they provide information to medical professionals on how to use new or unusual drugs. According to the pharmacists, this is an important factor in being able to effectively use the array of drugs that are provided as humanitarian aid.

### ***The Armenian healthcare system***

The Armenian healthcare system is organized according to the former USSR model, where patients are assigned to a polyclinic and then sent for specialized services or hospitalization to the referral institution for that polyclinic. All healthcare professionals are government employees, and all facilities are owned and operated by the government. Professionals who

were interviewed said that they are used to centralized management and provided examples of how they share scarce resources.

For administrative purposes, the country is divided into 10 “Marz” (large areas or districts) and the capital city of Yerevan, which has Marz status. Marz areas range in population from 67,900 to 401,300, with a median population of approximately 315,000. The 10 Marz, in turn, are divided into 35 health service areas. Yerevan is divided into 8 health service areas. In addition to Yerevan, with a population of 1.25 million, there are two other main cities: Gyumri and Vanadsor. Healthcare is organized by region, with tertiary and secondary hospitals providing the bulk of inpatient care and polyclinics providing the bulk of ambulatory care. The polyclinics are under the supervision of the hospitals. Specialty hospitals are regionalized as well.

As depicted in Table 5.1, in the late 1980s the country had a relatively large supply of hospital beds and professionals, including pharmacists, and a high diphtheria, pertussis, and typhoid (DPT) immunization rate, when compared with the United States and one of the other field study countries, Tanzania.

The population of Armenia exhibits the infectious disease patterns that accompany war—including breakdown of sanitation, water, and food supplies. Examples of infectious diseases encountered are diphtheria, polio, hepatitis A, hepatitis B, cholera, malaria, meningococcal meningitis, rabies, and even plague. The degenerative disease patterns of developed countries are prevalent in older Armenians (11.3 percent of Armenians are over 60).

Prior to 1991, health services were entirely financed by the central government from tax revenues. During the pre-democracy era, health facilities received regular allocations of operating and capital expenses in the annual budgets of the central and municipal governments. As a result of a drop in economic activity and in tax revenues, government funding has been insufficient. Government funds arrive sporadically, so that physicians, hospitals, and polyclinics often lack drugs, medical supplies, and capital for equipment, renovations, and new construction. Medical professionals and other employees of healthcare institutions continue to receive their government salary checks irregularly.

While health facilities are funded as part of the annual government budget, hospital managers who were interviewed during the field survey reported not receiving payments for drugs because of a lack of funds. The respondents emphasized that managers have very few opportunities to raise funds to pay for drugs and other operating expenses. They therefore

rely almost entirely on donations for their supply of drugs, supplemented by the insignificantly small amounts of funds they can raise from renting space to food stands or other businesses on hospital or polyclinic grounds (\$US400 to 800 per year per facility). These supplemental funds are used to purchase needed drugs in Russia.

In 1996 the Ministry of Health began working on restructuring the healthcare system to allow for cost-sharing by patients and thus to provide some funds for the supply of drugs and equipment, as well as for staff salaries. This transformation to a healthcare system where patients can choose their healthcare provider and where they will share costs for physician visits, drugs, and ambulatory and inpatient care will take a few years, according to the current minister of health. The minister also indicated that he plans to shift services from inpatient to outpatient care and to reduce the supply of inpatient acute care beds in the future restructuring of the healthcare system.

### **Limitations of the Field Study**

Because of the limitations noted below, the study cannot give a comprehensive picture of drug donations processes in Armenia. These limitations should be considered in any use and interpretation of the findings, especially regarding the robustness of the conclusions.

- The field study was carried out in one week with a limited number of interviews and limited access to recorded information on donated drugs from interviewed staff at health facilities and MOH.
- Observations on the delivery of supplies by plane, their inventory, and receipt at facilities are based on one air-cargo shipment of supplies on May 10–11, 1997, from the United States to Yerevan.
- An interpreter was used for all interviews and for reviewing all records on donated drugs that are kept in the Armenian and/or Russian language. Data on the proportion of drugs donated could not be verified directly by the interviewer.
- The geographic area covered in the interviews was concentrated around Yerevan, with the most distant facility being 50 km from Yerevan.
- The sponsors selected Armenia for the field study because a substantial proportion of its drug supplies is donated and a large proportion of these donations come from the United States. Armenia's donation processes may not be representative of those in other countries.

- Polyclinics, the providers of primary care, are under-represented in the sample.
- The informal sector and private delivery of care are not covered.
- While drug products were observed at facility pharmacies, no attempt was made to validate respondents' account books of drug stocks.

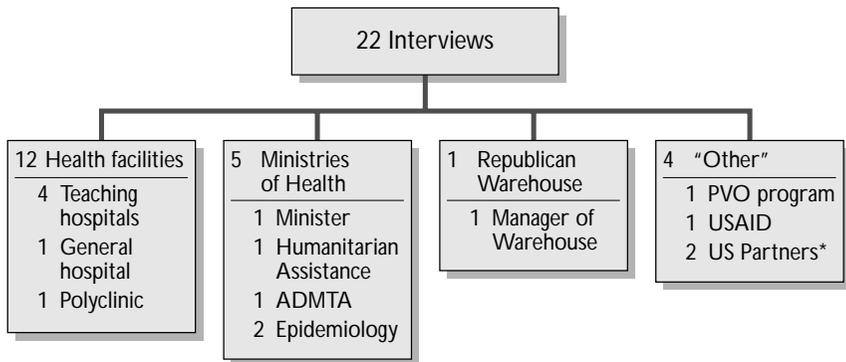
## The Study Period and the Profile of the Interviewees

The study was carried out from Saturday, May 10, through Friday, May 16, 1997. On Saturday, May 10, the analyst boarded a cargo plane loaded with medical supplies at Pease Airport in New Hampshire. The plane landed on Sunday, May 11, in Yerevan. All information was collected in face-to-face interviews at the Ministry of Health, the Republican Warehouse for Humanitarian Assistance<sup>9</sup>, health facilities, and at the US Agency for International Development office in Yerevan. An interpreter from MOH assisted with the interviews. In addition, two "Partners" were interviewed in the United States in June 1997.

The interviewees (Figure 5.1) were selected on the basis of information provided by several PVOs and by the WHO, with the intention of including individuals involved in the Armenian drug donations process and facilities of varying levels that received donated drugs. The donation process covered by this study includes:

FIGURE 5.1

### Profile of Interviewees



\* Interviewed in United States.

- *Health facilities:* These units receive donations from MOH and also solicit donations from PVOs, Partners, and individuals.
- *Ministry of Health:* According to MOH representatives, the Office of Humanitarian Assistance solicits 80 to 90 percent of all donations and provides permits for all remaining donations that are solicited by the institutions or provided by their Partners directly. The Armenian Drug and Medical Technology Administration is responsible for regulating all drugs in Armenia. The Office of Epidemiology collects data on the use of healthcare services in Armenia.
- *Republican Warehouse for Humanitarian Assistance:* The staff is in charge of processing and distribution of the donations solicited by MOH.
- Others include the *Armenia-based ambulatory pediatric care program*, a project funded and managed by overseas PVOs; the *US Agency for International Development*, whose staff facilitates commodities donations and transport; and *Partners* who donate drugs, and provide health-care services, training, and exchange of staff.

### The health facilities

The six sampled health facilities consisted of three tertiary-level hospitals in Yerevan, a secondary hospital located about 50 km from Yerevan, a specialty eye referral hospital in Yerevan, and one polyclinic in Yerevan. All facilities were selected because they were thought to be representative of other institutions throughout the country. In each institution, at least one administrator and one pharmacist were interviewed and the pharmacy was visited.

As previously noted, polyclinics are under-represented, and no dispensaries are included in the sample, but the hospital administrator at each of the selected hospitals is responsible for several polyclinics and dispensaries in his service area. These individuals, and the pharmacists working with them, were understood to be familiar with the supplies of donated drugs at their polyclinics and dispensaries. Each of the hospitals also routinely sends surplus or close-to-expiration drugs to its polyclinics. The profile of the health facilities is provided in Table 5.2.

### MOH and the Republican Warehouse

The following were interviewed at MOH: the minister; the deputy minister for epidemiology; the chief of the Department of Hygiene and

Epidemiology Control; the director of the Armenian Health, Drug, and Medical Technology Administration; and the director of the Humanitarian Aid Office. The manager of the Republican Warehouse was also interviewed (see Figure 5.2).

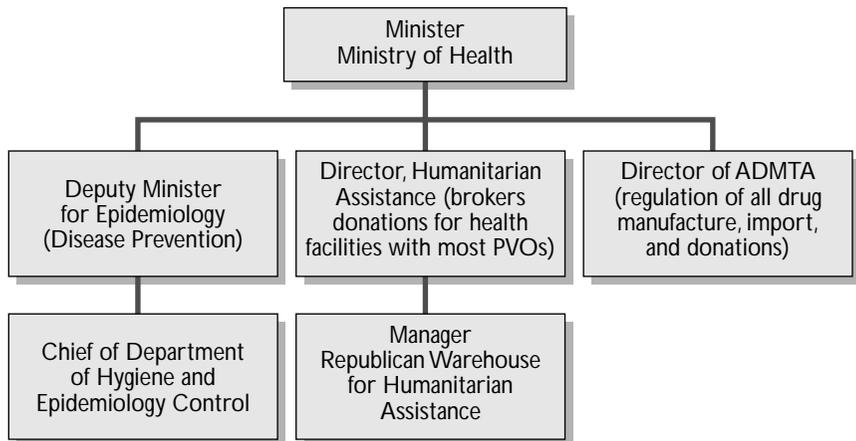
### Other interviewees

One US-based Diaspora PVO's resident manager was interviewed. The PVO is in the process of establishing a model ambulatory child health program. The resident manager and MOH staff in charge of the program described how the project will be completely supported by the PVO, from the construction of the building to the donation of the drugs used. Since the project is just being established, no information could be obtained about the type of drugs that will be donated to this program.

A representative of the US Agency for International Development (USAID) in Yerevan was also interviewed. The chief function of USAID office is to support humanitarian programs within the region. One way in which this mandate is carried out is by obtaining equipment and supplies from decommissioned military hospital facilities. Another way is to help arrange for military transportation or to provide direct funding for transportation.

FIGURE 5.2

### Profile of Interviewees in Ministry of Health and the Republican Warehouse for Humanitarian Assistance



T A B L E 5 . 2  
Description of Healthcare Providers in Armenian Sample<sup>1</sup>

Facility	Type (Service Area)	Medical Departments	Surgical Departments	No. Beds and % Occupancy	Ambulatory Visits/Year	Surgery	
						Inpatient Visits/Year	Ambulatory Visits/Year
No. 1	Major teaching hospital/trauma center (service area: City of Yerevan)	Neurology Intensive care Nephrology Gastroenterology Cardiology Pulmonology	Traumatology Neurology General surgery Thoracic surgery Urology	705 (70% occupancy)	100,000	4,000	NA
No. 2	Major teaching hospital (service area: City of Yerevan)	General medicine Neurology Obstetrics	General surgery Obstetrics Gynecology	400 (25–30% occupancy)	50,000	700 <sup>2</sup>	—
No. 3	Small general hospital (service area: nearest town)	General medicine Infectious diseases Pediatric	General surgery	110 (50% occupancy)	1,500	300–320	—
No. 4	Polyclinic (service area: City of Yerevan)	Adult and pediatric		NA	250,000	NA	300
No. 5	Children's (service area: City of Yerevan)	Gastroenterology Breastfeeding Neurology	Thoracic surgery Neurosurgery Traumatology General surgery	360 (60–70% occupancy)	7,500	800	NA

T A B L E 5 . 2  
Description of Healthcare Providers in Armenian Sample<sup>1</sup> (continued)

Facility	Type (Service Area)	Medical Departments	Surgical Departments	No. Beds and % Occupancy	Ambulatory Visits/Year	Surgery	
						Inpatient Visits/Year	Ambulatory Visits/Year
No. 6	Specialty eye hospital (service area: Armenia)		Children's eye surgery Traumatology Vascular and glaucoma surgery	210 (90% occupancy)	—	—	NA

— Data not available

NA = not applicable

1 Data based on interviewees' reports at each institution during the field study.

2 Includes 150 laparoscopic surgeries per year (cholecystectomies, appendectomies, extrauterine procedures, and others).

The representatives of two PVOs, an umbrella US-based Diaspora PVO and a large US PVO that supports healthcare programs and ships supplies to over 60 different countries, provided detailed shipping data for the May 10 shipment of drugs and supplies from the US to Armenia. The Partners of Facilities No. 1 (the trauma center) and No. 6 (the National Eye Center) were interviewed in the United States by telephone at the suggestion of the administrators of the respective facilities.

During the study, the analyst accompanied the supplies on a cargo plane from the point of assembly at Pease Airport in New Hampshire to their unloading onto trucks at Yerevan airport. Subsequently, the analyst was able to see the supplies stored and inventoried in the Republican Warehouse and to witness the stocking of supplies in one hospital pharmacy after that hospital picked up its shipment.

## **Description of the Current Donation Process**

### **Introduction**

The government of Armenia plays an important role in the donation process as the major “broker” between Armenia’s health facilities and overseas PVOs. The government solicits and screens pharmaceutical donations from PVOs, warehouses the incoming donations and then allocates and distributes the donations to health facilities for a token fee.

Representatives of the Office of Humanitarian Assistance (HAO) and the health facilities estimated that roughly 90 percent of all pharmaceutical donations are directly brokered by MOH. An additional 8 percent of pharmaceutical donations are obtained as a result of direct personal contacts by a health facility with a Partner overseas hospital or PVO. Also, individual professionals who come to Armenia for short periods to train physicians and nurses in specific medical techniques occasionally bring their own pharmaceutical supplies, which are estimated to account for the remaining 1 to 2 percent of all pharmaceutical donations. Overseas organizations that provide hospitals with cash or a credit for the purchase of drugs played virtually no role in humanitarian aid in the health facilities interviewed for this study.

### **Regulation of drug donations: role of Ministry of Health**

According to Armenian law, all donations of pharmaceuticals must be approved by MOH. According to the minister of health this central control and coordination of humanitarian aid within the ministry resulted from the difficulties experienced in organizing effective disaster

relief during and after the 1988 earthquake, when Armenia received a large volume of unusable supplies.

Armenia currently regulates the purchase, manufacture, importation, and use of pharmaceuticals with its National Drug Policy<sup>10</sup> and Essential Drugs List.<sup>11</sup> Armenia did not develop its own drug donation policy; instead, the National Drug Policy refers to the WHO *Guidelines*.<sup>12</sup>

### ***The Armenian national drug policy***

Armenia's National Drug Policy was adopted in October 1995. The policy was developed by the Armenian Drug and Medical Technology Administration (ADMTA) in consultation with experts from the ministry, Armenian professionals, and a consultative group from the World Health Organization.

The National Drug Policy governs drug selection, supply, financing and cost-recovery, production, quality, rational use, information, and human resources development. The majority of regulations of the policy are enforced by ADMTA, either through its inspection department or in its quality control laboratory. Four sections of the policy are of particular interest for the donation process:

1. *Donations*: The policy states that Armenia will follow the WHO *Guidelines for Drug Donations*.
2. *Fixed-dose combinations*: According to the policy, only those fixed-dose combinations that show proven advantages, such as increased therapeutic effectiveness, low cost, and better compliance, can be marketed in the country.
3. *Generic drugs*: The policy includes a section stating that only generic drugs will be procured, or at least only those brand-name drugs that have the generic name prominently displayed on the drug package, in order to encourage the use of less costly generic drugs in the country.
4. *WHO certification for the quality of drugs moving in international commerce*: The policy suggests that all drugs used in Armenia have WHO certification.

According to key officials, the National Drug Policy is being interpreted in light of the country's ongoing recovery from recent natural and economic disasters. It is being broadly interpreted now, with room for many exceptions. For example, the paragraphs on brand names and on fixed-dose combinations are currently interpreted as suggestions only, not

strict rules, and they have been routinely waived for donations. Similarly, the head of ADMTA said during the interview that he will waive the requirement of WHO certification if a donated drug was manufactured in the United States and received Food and Drug Administration (FDA) certification. In the future, ministry respondents suggest, these and other policy guidelines may be subject to stricter interpretation.

### ***The essential drugs list***

The Armenian Essential Drugs List (EDL) was developed by ADMTA with the advice of the National Essential Drugs Commission and the support of two other advisory bodies, the Pharmacological Commission and the Pharmacopoeia Commission. The current 1997 version is an update of the 1995 version, which in turn is a revision of two earlier versions.

The 1995 and 1997 Armenian EDLs include many drugs listed in the 1995 WHO Model List of Essential Drugs (WHO-ML)<sup>13</sup>. The Armenian EDL does not, however, include a provision for substitution of listed drugs by pharmacologically comparable drugs, as does the WHO-ML.

### ***The drug donation policy***

As outlined in the Armenian National Drug Policy, the HAO uses the WHO *Guidelines* to work with donors and organizations sponsoring airlift shipments. Humanitarian assistance, including drug donations, is the domain of the director of the Office of Humanitarian Assistance, who is physically located in the Ministry of Health but also has a position and responsibilities in the Ministry of Foreign Affairs. The objectives of the physician who currently occupies this position are to solicit sufficient quantities of appropriate donated drugs to guarantee an adequate drug supply for Armenian health facilities and to free up government resources for healthcare and other services. If a donation is offered that the director of HAO believes can be used appropriately by an Armenian health facility, he will (according to interviewees) make extensive use of the exceptions provided by the WHO *Guidelines*—for example, dating of the product, the generic name, and the WHO Certificate. He will ask ADMTA to clear such shipments so that pharmaceutical donations can be brought into the country.

The wording of the drug policy leaves room for judgment and changing circumstances, and, according to the director of HAO, the policy takes into account that in 1997 the foremost Armenian concern was to obtain an *adequate* supply of drugs. Since, according to MOH, the gov-

ernment has hardly any funds to purchase this supply, the ministry says that it will allow the donation of any drug it determines to be safe and efficacious and needed by healthcare providers.

### **Actors involved and logistics of the shipments**

According to two officials in MOH, about 30 to 40 percent of all drugs used in the country (that is, prescribed and over-the-counter drugs, in the public and private markets combined) are provided by humanitarian aid,<sup>14</sup> but we did not receive any written verification of this estimate. This study found that *within* the health facilities in the sample survey the estimated proportion of drugs that is donated is reported as much higher—approximately 80 to 90 percent for many therapeutic classes, according to the interviewees.

### ***Actors involved in MOH***

The Ministry of Health, directly and through the Office of Humanitarian Assistance, the Republican Warehouse for Humanitarian Assistance, and the Armenian Drug and Medical Technology Administration provide screening, coordination, distribution, and the regulatory framework for drug donations and approval for all donated drugs entering Armenia. HAO and ADMTA provide the Customs permits that allow a shipment to enter Armenia. In order to get an import permit, a potential donor must receive a fax approval from HAO that the drug is needed in Armenia in the amount offered. The donor also has to receive certification from ADMTA that the drug is appropriate for use in Armenia.

No duty is levied on donated drugs. All donated drugs brokered by MOH are stored in and distributed from the Republican Warehouse.

### ***The Minister of Health***

The minister, a surgeon, provides overall direction for drug policies within Armenia. All of the government agencies involved in the screening, warehousing, or distributing of incoming pharmaceutical donations fall within the purview of MOH. The minister ensures that all drug donations are approved by the staff by requiring donated drugs to have Customs permits. A donation of drugs has to be approved by the director of HAO, and the quality and appropriateness of donated drugs has to be attested by the director of ADMTA.

In addition, MOH, through the Humanitarian Assistance Program (comprised of HAO and ADMTA), acts as a broker on behalf of Armenian health facilities for donated drugs. At the same time, MOH realizes

that this program does not fully meet the drug needs of the country; accordingly, it welcomes attempts by health facilities to solicit donations directly from overseas to supplement the donations obtained by the ministry. MOH supports professionals and administrators who are able to solicit donations directly by facilitating import certification and shipping where possible.

MOH is considering a rule that would reduce an institution's budget by the value of donated drugs the institution received. There is concern, however, that this measure would reduce the incentive for hospital staff to solicit donations and, thereby, reduce the total amount of donations sent to Armenia. The minister of health has stated that he wants his staff to work closely with donors to optimize the usefulness of donations. In the interview, he repeatedly stressed the importance of Armenia continuously working with donors and learning more about the donation process.

### *The Office of Humanitarian Assistance*

The director of HAO, also a physician, reports to the minister of health but also has an office in the Ministry of Foreign Affairs. This dual accountability assures that all humanitarian and development assistance requests and offers, as well as international donations and loans that concern healthcare services and supplies, are coordinated by one person. Under his supervision, HAO coordinates all solicitations for and offers of donations, their delivery, warehousing, and distribution.

The director of HAO maintains that it is his responsibility to obtain the most useful donations in the most appropriate quantities and to safeguard the interests of all Armenians. There are times when the national interest overrides institutional interests, and he stated that in such a case he may have to disallow a donation that has been specifically requested by an Armenian healthcare institution. He has visited the United States several times for meetings with donors and to make presentations to PVOs. He has not, however, met with manufacturers.

The office has good working relationships with international agencies such as UNICEF and with major US PVOs and US Diaspora PVOs. The director of HAO both responds to offers for drug donations and regularly solicits specific items that are needed. To achieve an optimal mix and the most appropriate quantities of drugs through humanitarian aid, HAO collects annual statistics from all healthcare providers on the case mix of patients treated in each Armenian facility. Hospitals and polyclinics are also asked annually to submit specific lists of items they need to treat patients. Representatives in MOH say that they prefer major donations

to be made through HAO, so that it can distribute in a way that gives each facility an appropriate share of donated drug supplies.

In general, and according to our interviews, interpretation of the WHO *Guidelines for Drug Donations* and the Essential Drugs List is broad and flexible. If there is a recipient who can use a donated drug, then HAO will accept the donation. There are three characteristics of drugs that limit their acceptability as donations by the office:

1. expiration dates of less than three to six months, if the quantity cannot be used in that time;
2. prior expiration; and
3. lack of safety or efficacy, as determined by the HAO or ADMTA.

### *The Republican Warehouse for Humanitarian Assistance*

The Republican Warehouse is under the supervision of the director of HAO and is managed by a registered pharmacist. Its mission is to receive and inventory humanitarian aid from the donors and then, using the distribution list prepared with the director of HAO, to prepare the supplies for pickup by the 180 hospitals, polyclinics, and dispensaries. The products distributed from the Republican Warehouse include drugs, medical/surgical supplies, and equipment.

According to interviews, the Republican Warehouse obtains 90 percent of its drugs as donations and purchases about 10 percent as supplemental stock when donated funds are available. The manager reported purchasing specialized drugs, such as insulin or cyclosporin or a drug to treat Parkinson's Disease, as well as dialysis solution, when these are not available through donations. He purchases the majority of these drugs in Russia and Bulgaria, but cyclosporin is imported from Switzerland.

The planning cycle is one year. The Republican Warehouse prepares a year-end plan under the direction of HAO. The purchasing cycle is on average 30 to 40 days—that is, the warehouse will order insulin 32 days in advance of its restock date. According to the manager, the donation cycle for most products is longer, and there is far more uncertainty about the availability of drugs. The two large storage areas of the Republican Warehouse can hold two Boeing 737 cargo loads at a given time. At present the facility is not computerized and has very limited motorized equipment, such as forklifts, to stock and move supplies.

### *The Armenian Drug and Medical Technology Administration*

This administration is currently managed by a physician who was the

minister of health for 20 years. All donated drugs must have his Customs permit. The purpose of ADMTA is to safeguard the quality of all drugs, whether imported, donated, purchased, or produced in the country. The director's perspective on the drug donation process appeared to be influenced by two facts: (1) he was the minister of health who had to deal with the destruction of unusable drugs after the 1988 earthquake, and (2) it is his responsibility to safeguard the Armenian drug supply and to assure the identity and quantity of the active ingredient in imported and local drugs.

The director has been instrumental in the development of the Armenian Drug Policy and the Essential Drugs List, as well as the enforcement of the WHO *Guidelines*. In building the infrastructure for implementing the National Drug Policy of Armenia, he has developed standard treatment guidelines for selected conditions in cardiology, pulmonology, and gastroenterology. ADMTA is also developing a computerized formulary with the assistance of WHO, to provide on-line information on the drugs on the Armenian EDL and reasonable substitutes.

In order to enforce the quality standards for all imported and locally manufactured drugs, the laboratory of ADMTA randomly tests drugs. ADMTA is also in charge of licensing private pharmacies and of assuring that donated drugs are not sold to pharmacies. The small inspection staff (three people) checks the pharmacy shelves for donated drugs, while carrying out their licensing duties. The penalty for selling donated drugs is withdrawal of the pharmacy license and closure of the drugstore by ADMTA. Of the 500 to 600 private pharmacies in Armenia, four were found to have donated drugs on their shelves in the past two years. These pharmacies were subsequently closed by ADMTA.

### ***Logistics of MOH requests and shipments***

During the annual budgeting process in October and November, each institution submits data on its patient mix and a list of products it would like to receive. HAO then uses this list for negotiations with donors. In addition, each administrator of the roughly 180 institutions in Armenia will bring up requests with MOH staff when he or she has the opportunity.

HAO is in frequent communication with its donors, such as US-based Diaspora PVOs. HAO receives faxed notices of the types, quantity, and dating of products available from these and other PVOs. The director of HAO responds directly to the PVO or consults with a specialist if the product is not commonly used. If the product can be used, his faxed response will state what quantity of the product can be used within the product's expiration date; then HAO and the PVO discuss transport

options. HAO also sends lists of needed products to the PVOs. A MOH representative described the process as follows:

*The PVO we work with most often has been able to transform its work according to the needs and regulations of Armenia and, in turn, the PVO is teaching us how humanitarian requests might work better and be more effective. For example, when the PVO sends us a notice of the availability of a product, we respond within a day or two. If we need specific products, we let the PVO know. For example, we have a kidney transplant program. We get immunosuppressive drugs by letting the PVO know the volume we need. We also make sure that the PVO representative is informed about our healthcare programs and new initiatives, and we always plan tours of facilities and programs for the PVO representative who accompanies the cargo plane. When we change regulations and promulgate new laws which affect the type of drugs we will accept, we inform the PVO immediately. We are in daily contact with the PVO, and they in turn are in close contact with potential donors, including manufacturers, international organizations, and other PVOs in the United States.*

### *Shipment of donated drugs*

The preferred transportation method for donated drugs is via cargo plane because of the geographical location of Armenia. Other less frequently used options are shipment via cargo container and train (although these options are regarded as problematic due to the length of time involved).

There have been 97 airlifts by one US PVO to Armenia since the 1988 earthquake. From the time of the initial earthquake response to the end of 1996, there were three to four airlifts per year. In 1997 a monthly cargo flight began, sponsored by a US benefactor of Armenian origin. Interviewees indicated that if these flights continue to take place regularly with a known schedule and with known content, these shipments will greatly reduce the logistical difficulties created by sporadic drug shipments with limited advance information on the contents. The airlifts contain the products solicited by the Diaspora PVOs and major US PVOs, which also solicit the airlift fee. Donations from individuals and Partner institutions are also shipped during such airlifts.

Airports in Florida and New Hampshire that deal primarily with freight have been used in the past. At the airport, the boxed supplies are checked against the bill of lading, loaded onto metal pallets, shrinkwrapped, and tied with heavy netting. Drugs requiring refrigeration are loaded into a

separate compartment, which is accessed from below. The objective of this process is to assure the optimal use of the cargo space and to reduce opportunities for pilferage.<sup>15</sup>

HAO has developed a speedy Customs process to minimize the ground cost of the airplane and the time that donated drugs are exposed to the elements. During the May airlift, the donated supplies were inspected by Customs upon arrival, unloaded from the pallets onto MOH trucks, and transported immediately to the Republican Warehouse. Refrigerated drugs were loaded into refrigeration trucks.

While the plane was unloaded, Customs officers inspected the bills of lading and MOH permits. According to the director of HAO and the US-Armenian PVO representative, the process had become smoother with each successive cargo flight, so that it now takes only four to five hours to clear and unload the plane, load the trucks, and transport the supplies to the Republican Warehouse. During the May 1997 shipment, this process took four hours.

Officials from MOH and HAO indicate that they take care to assure that, throughout the centralized donation process, all transactions are open and public, without preferential treatment of any individuals or facilities, and that opportunities for diversion are reduced. Each cargo shipment is inventoried by a different committee of volunteers at the Republican Warehouse. Depending on the size of the shipment, the inventory process takes two to three days.

The members of the volunteer committees change for each shipment. They are staff from healthcare institutions, MOH, and other persons. According to the director of HAO and the manager of the Republican Warehouse, rotating the staffing for the inventory process provides three advantages: First, it exposes the volunteers to the process of donation, including the full spectrum of the products that are received and the hard work required to process the donations; second, it assures transparency of the process of conducting the inventory and sorting supplies according to the distribution plan of HAO; and third, it prevents product diversion to private markets. Once inventoried, the drugs are sorted by healthcare institutions according to the list prepared by the director of HAO and the manager of the Republican Warehouse—a process that takes several days. The drugs are then picked up by the institutions.

The turnaround time for the May cargo flight was five to six days for the closest hospitals. The plane arrived on Sunday, and the drugs were ready to be picked up by the pharmacy on Thursday or Friday. For some institutions, the distance to Yerevan is over 300 km, and poor road

conditions can make it an eight to 10 hour trip. The health facilities pay a handling fee to the Republican Warehouse of two cents for each US\$10 of the assessed value of the donated drugs. The assessed value constitutes 20 percent of the drugs' Armenian generic wholesale price.

### ***Donated drugs solicited by institutions***

Health facilities often maintain their own pipelines to solicit drug donations. The most important sources are contacts with specific nonprofit organizations overseas and contacts with individual professionals or institutions. The institutions write or fax their requests to their Partners overseas, then typically receive the requested drugs within a few months' time via airlift or mail or hand-carried by an individual. An import permit must be obtained from HAO and ADMTA, regardless of the mode of transport. There is no charge for this permit and no import duties are levied on donated drugs.

The major problem with these donations is that the amounts of drugs are typically small. The same is true for drugs provided by specialists who come to Armenia to train colleagues for a week or two. These individual requests are time-consuming for the recipients, and their financial cost in terms of faxes and phone calls can be high; also, the predictability and regularity of the shipments are low. However, the ultimate recipient, that is—the professional in the Armenian institution—has direct communication with a donor and thus feels that he or she can influence the type of product that will be received.

A secondary problem can arise if the Partner has not obtained the necessary permits from HAO and ADMTA to import the drugs. In one case, a US Partner reported during a telephone interview that he had been able to obtain two boxes full of critical but short-dated drugs from his US hospital and suppliers at no cost, to be hand-carried to Armenia. On arrival at Yerevan airport, after the 20-hour trip, the donor had to wait for five to six hours at Customs (due to the short expiration date and the lack of the required import permit) before a representative of the hospital was able to get the officials to release the drugs and the professional. After this November 1995 incident the US Partner decided to no longer solicit donations of drugs, and to restrict donations to medical supplies.

### ***Unsolicited drugs sent to institutions***

In this survey, only one institution reported receiving unsolicited drugs in 1996. The director explained that unsolicited donations were a problem in

the past, and the donations received in 1996 were a remnant of this process. The facility did not report receiving unsolicited donations in 1997.

### Sources and characteristics of the donated drugs

#### *The sources of drug donations for health facilities*

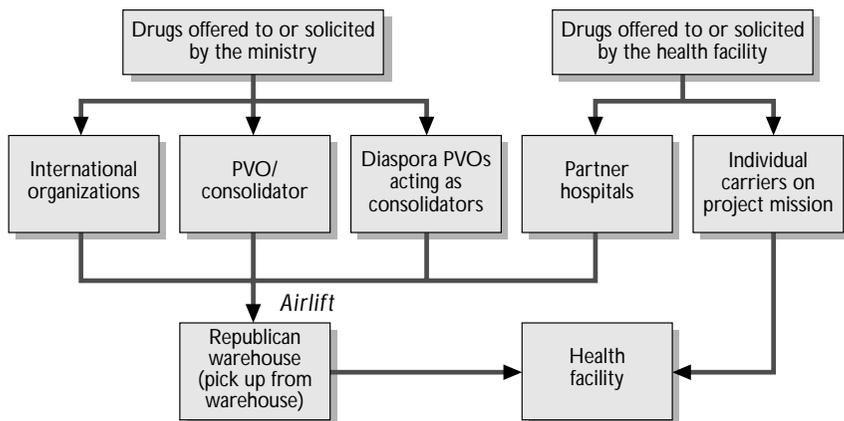
By region of origin, North America was the most important source of Armenian drug donations in 1996 and 1997, according to those interviewed. Officials in MOH and administrators in the health facilities said that 80 to 90 percent of all donations came from the United States and Canada, with the remaining originating in Europe (France, Great Britain, Germany, and Italy). Respondents indicated that PVOs were the principal source of pharmaceutical donations received in Armenia in 1997, supplying 90 percent of the total. The 10 percent of drug donations not provided by PVOs were sent by overseas Partner institutions and by individuals. The Armenian Diaspora played an important role in soliciting donations and in providing substantial logistical assistance to the other PVOs.

The six main sources of drug donations identified by the respondents are shown in Figure 5.3:

1. The Ministry of Health, Office of Humanitarian Assistance<sup>16</sup>
2. UNICEF
3. Armenian PVOs located in the United States

FIGURE 5.3

#### Health Facilities: The Drug Donation Receiving Process



4. Other PVOs in the United States and Canada
5. Partner hospitals
6. Individuals

The five hospitals and the polyclinic surveyed perceived the majority of their donated drugs as stemming from HAO, which in turn obtains most of its drugs from US PVOs. In addition to this source, UNICEF provides vitamins and vaccines for children and pregnant mothers. Several of the smaller hospitals reported that they occasionally receive small amounts of short-dated, overstock or unneeded items from some of the larger Armenian hospitals.<sup>17</sup>

### ***General characteristics of donated drugs***

As stated by the minister, it is the objective of MOH to cover as much as possible of its drug needs with donations, in order to free up scarce resources in the healthcare sector. According to the director of HAO, MOH's priorities are as follows (not ranked in order of importance):

- Trauma, emergencies
- Immunizations
- Maternal and child health (from zero to seven years of age)
- Social and communicable disease, such as tuberculosis, diabetes, and sexually transmitted diseases
- Hematological and oncological diseases
- Diseases affecting the elderly

HAO is therefore soliciting three broad categories of drugs and pharmaceutical products:

1. Drugs that meet the basic need of hospitals and polyclinics, such as analgesics, including morphine and codeine; antipyretics; antibiotics; drugs to deal with acute phases of infarcts, as well as with chronic heart conditions; IV solutions; dialysis solutions; drugs for dermatologic problems, including antibiotic ointments; a continuous supply of insulin for patients with diabetes; a broad spectrum of drugs to treat tuberculosis; and vitamins for pediatric and prenatal use.
2. Drugs that could be considered more "sophisticated," newer and possibly more expensive, including drugs that may be prescribed for specific,

limited conditions, such as broad spectrum antibiotics (for example, ceftriaxone, clarithromycin and others); drugs to deal with heart attacks, such as andrenergic blocking agents; newer calcium channel-blocking agents like amlodipine, felodipine, and isradipine; drugs for patients with Parkinson's disease; drugs for patients who received organ transplants; and newer drugs to treat HIV-positive patients.

### 3. Vaccines to cover the immunization needs of the population.

While HAO is generally able to obtain all three types of drugs when soliciting donations, the bulk of PVO shipments consist of drugs that meet the basic needs of hospitals and polyclinics. There usually are some of the more "sophisticated" drugs included. The greater portion of vaccines is supplied by UNICEF, although shipments by PVOs have also contained vaccines. UNICEF also provides vitamin tablets.

According to the respondents in this field survey, the volume of donated drugs received does not meet all the needs of the facilities. Interviewees estimated that drug donations in the past year actually met between 25 and 50 percent of the drugs desired by the facilities, reflecting the possibility of significant drug shortages. The author of this chapter did not receive any documentation to support the estimated drug needs, the extent of the shortages, or the percentage of drug consumption accounted for by donations.<sup>18</sup>

#### *Type of drug requested and donated*

Healthcare facilities in Armenia receive drugs from HAO based on the submitted description of their patient mix, their special requests, and the drugs that are donated. The healthcare institutions prepare an annual budget plan. The director of HAO tries to solicit drugs that meet hospital and patient needs, but, according to the interviewees, the volume of donations and the types of drugs obtained through humanitarian assistance never fully meet the need. Donated drugs frequently differ in type and strength from one shipment to the next. Past shipments have contained anesthetics; analgesics; antibacterials such as ampicillin, penicillin, ciprofloxacin, amoxicillin, tetracycline; cardiovascular drugs; ointments; ophthalmological preparations; oral rehydration salts; cough suppressants; and vitamins. Several large shipments of a fixed-dose combination of an analgesic and decongestants were also received.

According to HAO, the increased frequency of airlifts appears to have broadened the choice of drugs that are available, and is expected to increase the volume in the future.

The efforts of HAO to obtain specialized drugs have often been successful, according to MOH. The country has 160 kidney transplant patients, both pediatric and adult. The cyclosporin for these patients was purchased from Switzerland in the past. As government funds currently are scarce, immunosuppressives are now being obtained through humanitarian assistance channels. The May 1997 air cargo shipment contained donated immunosuppressives and antineoplastics, as well as antibacterials, anti-Parkinson drugs, cardiovascular drugs, anesthetics, analgesics, and vitamins and electrolytes.

In the past, the combination of l-dopa and carbidopa, a standard treatment of Parkinson's disease, was occasionally purchased by the polyclinics. Because of a shortage of funds, the director of HAO has solicited anti-Parkinson disease drugs from US-based Diaspora PVOs. The May 1997 shipment of donations also included 35,500 bottles of an anti-Parkinson drug that had been requested. According to the director of HAO, this donation will make it possible to treat all Parkinson patients in Armenia for a year. This drug donation was valued at \$4.8 million by the US PVO.

During the interviews, each administrator and pharmacist was asked what proportion of all drugs the hospital used had been donated. The response of the interviewees at the large teaching and specialty hospitals was usually based on their review of stock records. They estimated that overall, between 80 and 90 percent of their drugs were donated. The small general hospital (Facility No. 3) and the polyclinic (Facility No. 4) relied almost entirely on donations. Interviewees at the health facilities were then asked to provide the same information for each of the classes of drugs they currently used. In many drug categories, they had not received any donations, and often they also did not have any drugs on hand from other sources. Table 5.3 presents donations as a percentages of drugs used in each of the 27 major drug categories of the Armenian Essential Drugs List. Table 5.4 lists respondents' examples of drugs on hand from donations, as well as drugs sought through donations.

Not included in Table 5.3 are donations from the larger hospitals to the small community hospital and the polyclinic, Facilities No. 3 and No. 4. The larger hospitals provided drugs that were about to expire or had been received in excess to small hospitals and polyclinics in their service area. Table 5.5 provides a list of drugs obtained by the Partner of the large teaching trauma and emergency center (Facility No. 1) for the Armenian facility. The sources of donations were the Partner's US hospital, US colleagues, and his US hospital's drug suppliers.

TABLE 5.3

**Donations as a Percentage of Drugs Used,<sup>1</sup> by Drug Class, Estimated by Interviewees in Four of Six Surveyed Armenian Facilities, May 1997**

By Classes	Facility No. 1 <sup>2</sup> (%)	Facility No. 3 (%)	Facility No. 4 (%)	Facility No. 5 (%)
1. Anesthetics	0	0	NA	30
2. Analgesics	20	100	60	70
3. Anti-allergics	50	0	85	9
4. Antidotes	0	0	— <sup>3</sup>	0
5. Anti-convulsants	0	0	— <sup>3</sup>	— <sup>3</sup>
6. Anti-Infectives	5	100	85	100
7. Anti-migraine drugs	0	100	0	80
8. Anti-neoplastics, immunosuppressants	NA	NA	— <sup>3</sup>	NA
9. Anti-Parkinsonian drugs	0	NA	— <sup>3</sup>	NA
10. Drugs affecting blood	0	0	100	100
11. Blood products, plasma substitutes	0	100	NA	— <sup>3</sup>
12. Cardiovascular drugs	40	100	50	NA
13. Dermatological products	0	0	100	0
14. Diagnostic agents	100	0	NA	60
15. Disinfectants, antiseptics	80	0	100	50
16. Diuretics	2	0	60	70
17. Gastrointestinal drugs	100	0 <sup>5</sup>	90	80
18. Hormones, etc.	0	0	— <sup>3</sup>	80
19. Immunologicals	0	0	100 <sup>4</sup>	— <sup>3</sup>
20. Muscle relaxants	0	0	NA	0
21. Ophthalmological drugs	NA	NA	80	NA
22. Oxytocics	0	100	NA	NA
23. Peritoneal dialysis solution	NA	NA	NA	NA
24. Psychotherapeutics	0	0	2	100
25. Respiratory tract medications	50	0	80	80
26. Intravenous solutions	70	100	90	70
27. Vitamins and minerals	100	100	100	80

NA = not applicable, (not used at this hospital).

1 0 = no portion of used drugs stemmed from donations; 100 = all used drugs were donated, regardless of the extent to which used drugs met the drug needs.

2 Percentage of all drugs available in Facility No. 1, amounted to only 25% of all drugs needed.

3 Did not receive until last two shipments, "desperately needed" (respondents' term, ed.).

4 Vaccines against diphtheria; no others.

5 Obtained oral rehydration salts from other hospital.

TABLE 5.4

**Examples of Drugs on Hand from Donations, Products Sought, and Comments Made by Interviewees at Six Health Facilities, May 1997**

Facility No.	Examples of Drugs on Hand from Donations	Drugs Sought
No. 1	Ibuprofen with decongestant (large amount); naproxen; ibuprofen (expired 8/96); sulfamicilline (from France, expired 11/96, all hospitals received large amount of tablets which they could not trade; would have preferred half injections); codeine. May 1997 shipment: dexamethasone sodium phosphate; anti-inflammatory asthma medication (with 1.5 months shelf-life left, will be used up in 10 days for 40–50 patients); naproxen (large amount); halothane.	Ampicillin; ceftriaxone; clarithromycin; isradipine; antifungal tablets; contrast diagnostics; dextran; polygeline; antibiotic ointments; anti-scabies drugs; loperamide; atropine; butylscopolamine; morphine. (Need more of everything; currently only have 25% of drugs needed on hand.)
No. 2	Ibuprofen with decongestant. May 1997 shipment: gentamicin; cefazolin; ampicillin; dextrose.	3rd and 4th generation antimicrobials. (Need more of everything).
No. 3	Ibuprofen with decongestant (large amount). (“Too little of everything else.”)	Anesthetics and pre-operative medications; opioid and non-opioid analgesics (acetaminophen); antihistamines; broad-spectrum antibiotics; IV solutions; cardiac drugs; injectable vitamins; anti-ulcer medications; cancer chemotherapeutics.
No. 4	Ibuprofen with decongestant (large amount). (Short stocks on all other drugs.) Drugs against bronchial asthma cancer pain relievers; hormones; anticonvulsants.	Antibiotics; cardiovascular medications; gastro-intestinal drugs;
No. 5	Ibuprofen with decongestant; analgesics; anti-allergics; anti-infectives; diazepam; haloperidol; gastrointestinal drugs; psychotherapeutics; IV solutions; vitamins. (Short on everything except ibuprofen, naproxen.)	3rd and 4th generation antimicrobials; anesthetics; anticonvulsants; blood products; immunologicals.
No. 6	Ibuprofen with decongestant, propine eyedrops; captopril; dopamine; sodium nitroprusside; nicergolin.	Antiviral eyedrops; items which are not on the Armenia EDL;

TABLE 5.5

**Drugs Provided by Partner of Trauma Hospital  
(Facility No. 1) (1992–1995)**

Date	Drug	Value Using US\$ Purchase Price <sup>1</sup>
10/93	Antibiotics	362
	Cefadroxil	1,247
5/94	Isoniazid	5,000
	Antibiotics	3,000
	Cefadroxil	2,880
	Rifampicin, 12,000 tablets	28,200
	Streptomycin, 468 @ 10 ml	17,500
	Isoniazid, 168,000 tablets	15,502
	Rifampicin, 6,000 tablets	15,600
	Streptomycin, 8,160 vials	35,000
Pyrazinamide, 6,000 tablets	4,800	
6/94	Pyrazinamide, 6,000 tablets	4,800
10/94	Streptomycin	1,796
	Human insulin	5,430
	Isoniazid, 24,000 tablets	
11/95	Streptomycin	576
	Isoniazid, 100 mg, 180,000 tablets	10,377
	Isoniazid, 300 mg	7,200
	Antibiotics	2,000

<sup>1</sup> Value estimated at the time of donation.

According to the pharmacists interviewed, third- and fourth-generation antimicrobials were in short supply in all hospitals visited. The other drugs supplied by the US Partner of Facility No. 1 target two disorders: diabetes and tuberculosis. In a telephone interview conducted in the United States, the Partner said it was a coincidence that the drugs that were hand-carried into Armenia addressed these two diseases.<sup>19</sup>

The Partner of Facility No. 6 said that some products are difficult to get, such as antiviral eye-drops to treat herpes simplex infections. On the other hand, propine eyedrops for glaucoma are frequently donated, but because of its side-effects, it is not the first choice of the director of the facility. During the 1997 study visit, two cabinets of propine with a 1996 expiration date were observed. They had been shipped by a major Diaspora PVO, and had been received with four and a half months left before expiration. When asked why this drug had not been destroyed, the head of the hospital answered that there had been no opportunity to destroy it, and that in an emergency it could still be used, because professionals in

the field know that it has a longer actual shelf life than the “official” one stamped on the box.

### *Donated drugs compared with the EDL*

The Armenian EDL follows the WHO Model List of Essential Drugs, but it does not indicate any alternative medications. As far as HAO is concerned, however, the EDL was primarily developed for drug purchases and manufacturing in Armenia. Thus, any donation that is a reasonable substitute (in the opinion of the director of HAO) for a drug on the Armenian EDL or the WHO-ML is acceptable.

The head of HAO said that he had not had to refuse any drug donation in the past two years when he used the WHO-ML as standard, because the list is current, being revised frequently, and the list is inclusive, providing many alternatives.

### *The expiration of donated drugs*

The time prior to expiration of drugs was examined at each health facility visited. Table 5.6 presents estimates of the percentages of donated drugs with differing expiration times on arrival at the facility. These data are estimates obtained from the 12 health facility managers and pharmacists during the field study in Armenia. The data were not validated.

From the estimates listed in Table 5.6, it appears that the small general hospital (No. 3) and polyclinic (No. 4) receive somewhat shorter-dated

TABLE 5.6

### Estimated Percentages of Total US Donated Drugs with Differing Expiration Dates on Arrival at the Facility

Dating <sup>1</sup> on Arrival at the Facility	Facility (%)					
	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6 <sup>2</sup>
< 3 months	—	5	10	5	5	—
3–5 months	—	10	30	30	5	—
6–8 months	—	50–60	30	30	15	—
9–11 months	100	25	15	30	15	—
1 year+	—	—	15	5	60	100
Total	100	100	100	100	100	100

1 Dating refers to the time remaining before the expiration date of the drug.

2 The response by the administrator and the pharmacist of Facility No. 6 was probably not correctly translated or noted, because during the May field Survey, a large volume of drugs were found on the shelves which had been received last year with less than six months dating.

drugs than the other facilities. Between 35 and 40 percent of the donated drugs of the small general hospital (No. 3) and the polyclinic (No. 4) are said to have dating of less than six months on arrival, compared with no drugs with less than six months dating in the trauma center (No. 1) and the eye referral hospital (No. 6), 15 percent in the smaller teaching hospital (No. 2) and 10 percent in the children's hospital (No. 5).

The most important reason for the difference in dating seems to be that the larger hospitals give short-dated or overstock drugs they have received from HAO to the polyclinics and community hospitals, after these drugs have already been in their hospital pharmacy for a few months. All four large hospitals said that this was their practice.

There were expired drugs on the pharmacy shelves of each institution that we visited. The interviewees cited two reasons for keeping these drugs on the shelves. First, expired drugs can be destroyed only once or twice a year, because a representative of ADMTA has to be present. They usually are burned in the synthetic rubber factory, and the facilities must wait until the incinerators are fired to a temperature above 1000 degrees Fahrenheit. Sometimes they burn expired drugs on hospital grounds, but they stated that they generally try to avoid this practice. Second, expired drugs are kept as a hedge. We were told that, in general, expired drugs are not administered to patients. In each institution, however, we were also told that on some occasions when no current drugs are available, the prescriber prefers an expired drug to no drug at all. In the case of one facility, when some drugs expired on the shelves, the director had them tested to see whether they still contained the required amount of the active ingredient. They did, and so they were used. The director felt that he and his pharmacist acted in the best interest of the patients, and with all necessary precautions.

### *Other characteristics of donated drugs*

Armenian pharmacists are reportedly able to read labels in Armenian, Russian, English, German, Italian, and French. Difficulties may arise for the occasional donation labeled in an Asian language. It is estimated that less than 1 percent of donated drugs in the surveyed pharmacies were labeled in a language unfamiliar to the pharmacist. Many of the drugs are administered within the institution.

Donated drugs that are given to patients are provided with written instructions. Most European drugs have package inserts, written for the patient and detailing indications such as side-effects. The patients are usually given these inserts, according to our interviewees. To the extent

that the patient is using a drug that originated in the United States, and that either does not have such a package insert or has one written only in English, the patient does have less information than if the drug package originated in Armenia or Russia. However, the physicians and pharmacists said that they usually provide both verbal and written information and instructions.

In the pharmacy surveys, donated drugs from the United States were observed to be fully labeled, including the international nonproprietary names (INN). They were dated and had batch numbers so that they could be traced. Most drug products found on the pharmacy shelves for donated drugs in the six facilities that were visited were brand-named products in small, individual boxes, designed to last for one course of treatment. An estimated 10 percent of donated drugs came in large hospital-size containers of tablets. According to the pharmacists, Armenian patients are used to small, individual brand-named packages for their home use and are not familiar with tablets repackaged into plastic vials, small bags, or boxes. Both providers and patients prefer small brand-named packages. Only one of the six facilities had plastic vials for repackaging available.

### ***Costs of drug donations for the recipients***

Administrative and management costs are incurred by MOH and by the Republican Warehouse. Hospitals and ambulatory care providers incur financial costs in the form of the fee required by the warehouse. They also incur some administrative and management costs. The ultimate consumer, the patient, does not pay for donated drugs in health facilities.

### ***Health facilities and ministry***

***Financial costs: cash outlays for donations by facilities.*** The financial costs of drug donations incurred by hospitals and ambulatory facilities for donations depend on whether the donation is brokered by HAO or the institution solicits the donation directly. In no case, however, did the Armenian institutions we interviewed pay for shipping or Customs duties for donated drugs.

Costs for donations brokered by HAO are low, because MOH imposes only a minimal handling charge, equivalent to two cents per \$10 of the assessed value of the donated drug. The director of HAO calculates the handling charge as follows: He assesses the value of the donated drug at 20 percent of the Armenian wholesale price of the generic equivalent of the donated drug. Of the assessed value, the handling fee is 0.2 percent of the value he assigns to each donation, or 0.04 percent of the Armenian

wholesale price. The handling fee is paid to the Republican Warehouse. While the health facilities have almost no access to cash, they did not report this charge for donated drugs as an obstacle to obtaining needed drugs, as it is usually deducted from their budget throughout the year. However, they were concerned about the opportunity costs of spending even small amounts on any donated drugs that do not match their priorities or that might expire before they can be used.

Costs for donations solicited by the institution tend to be higher because they involve overseas phone calls, faxes, and sometimes e-mail. However, the institutions do not pay for freight or import duties. Eventually, it is hoped that health facilities will generate income through patient cost-sharing for drugs, and that these funds can be used to supplement the donations with purchased drugs.

*Time costs: routine, bartering, and logistical costs.* Initially, routine time costs are relatively low for donations received via the Ministry of Health. The facility has to provide MOH with data on its patient case mix between one to three times per year. Occasionally, the facility will be asked if it can use a specific drug. There are, however, two time costs that can be high: that of bartering for different drugs with other institutions and that of using donated drugs.

Because donations often do not meet the institution's exact needs, the institution has to resort to bartering of drugs with other institutions and, sometimes, with private pharmacies. This takes a great deal of time, according to our interviewees. The institution also incurs costs in using donated drugs. Because drugs often are not exactly what the hospital needs or the same as in the last shipment, the pharmacist needs to train physicians and post information on how to use varying drugs. In some cases the pharmacist and physicians have to determine how to switch chronic patients from one drug to another. Often the pharmacy runs out of drugs because a new shipment lacks one vital drug the institution has received in the past. The administrator and pharmacist also have to plan their purchases carefully with their limited resources, so as not to purchase a drug they might receive as a donation during the year. According to the health facility managers and the pharmacists interviewed, these time costs are substantial. In their opinion, obtaining the majority of drugs through donations is not a feasible approach for the long run.

*Costs of donated drugs for the patients.* In 1997, interviewees reported providing all hospitalized and ambulatory patients with drugs free of charge if donated drugs were available. When donated drugs were not

available, patients were asked to purchase drugs at a private pharmacy off-premises. According to all facility officials interviewed, providers try to reserve the donated drugs for the very poor whenever possible.

## **Perceptions of the current drug donation process by the recipients**

During the field study interviews, officials at the health facilities and the Ministry of Health were asked about their perceptions of the current drug donation process.

### **Regulations on drug donations**

In interviews, health facility managers stated that they respect the government's efforts to regulate donations for the following reasons:

- Healthcare providers stated that they trust the government and its role in managing Armenia's healthcare services and in developing rules for drug donations.
- Healthcare managers stated that MOH regulations (which include the WHO *Guidelines*), which could reduce the level of donations, have not done so since HAO has implemented them selectively and flexibly. The director of the Office of Humanitarian Assistance has used the exceptions in the regulations including, for example, authorizing the donation of drugs with less than 12 months dating and drugs that are not listed on the EDL.
- Administrators and pharmacists stated that they share (and barter) among facilities donated drugs that do not meet the needs of a facility to which they were allocated.

Hospital administrators stated that they accept the regulations, even if they disallow some donations, as long as they improve the overall quality of the donation process.

### **Benefits and drawbacks of the current drug donation process**

#### ***Overall perceptions***

According to the interviewed health facility managers, pharmacists, and MOH officials, the drug donation process provides drugs to health facilities where very limited pharmaceutical supplies would be available without donations. The current donation process, as managed by MOH, is considered to treat health facilities fairly, according to the health facility

managers surveyed. Given the enormous task of obtaining donations to cover a large percentage of all drugs used and prescribed by government in-patient and out-patient facilities, the survey respondents feel that the advantages of the current Armenian donation process outweigh its drawbacks. Table 5.7 provides an overview of the perceived benefits and drawbacks of the donation process and of donated drugs according to the health facility administrators, pharmacists, and government officials. These reported benefits and drawbacks (which were not verified) are discussed in the following two sections.

### ***Perceived advantages***

#### ***The centralized donation process helps***

The centralized donation process helps managers and officials to obtain useful drugs. The MOH and the health facilities were generally pleased

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T A B L E 5 . 7

### **Benefits and Drawbacks of the Donation Process and Donated Drugs as Perceived by Health Facility Managers and Government Officials**

Perceived Benefits	Perceived Drawbacks
<p><i>Centralized process helps to:</i></p> <ul style="list-style-type: none"> <li>• Obtain useful drugs.</li> <li>• Assure low cost donations.</li> <li>• Simplify the logistics of getting drugs.</li> <li>• Promote equity.</li> </ul>	<p><i>Lack of input by health facilities:</i></p> <ul style="list-style-type: none"> <li>• Insufficient input into solicitation process.</li> <li>• Insufficient input into allocation of donations.</li> </ul>
<p><i>Donated free drugs:</i></p> <ul style="list-style-type: none"> <li>• Help poor patients maintain access.</li> <li>• Save resources in government budget.</li> </ul>	<p><i>Drug donations are insufficient:</i></p> <ul style="list-style-type: none"> <li>• Type and volume of drugs unpredictable.</li> <li>• Type and volume of drugs do not meet need.</li> <li>• Logistics of drug management difficult, some waste.</li> <li>• Data not sufficient at central and facility level.</li> </ul>
<p><i>Process allows for direct solicitations by facilities:</i></p> <ul style="list-style-type: none"> <li>• Of specific, scarce, expensive drugs.</li> <li>• Without import duties, and government charge for directly solicited donated drugs that provide additional resources to the facility.</li> </ul>	<p><i>Lack of transparency of donation process:</i></p> <ul style="list-style-type: none"> <li>• Overseas donation process not clear to health facility managers.</li> <li>• Armenian regulatory process not clear to overseas partners.</li> </ul>

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with the drugs being obtained by the donation process. According to those interviewed, centralizing the process has improved the supply of needed drugs and extended the average expiration dates of arriving drugs. The minister of health maintained that managing donations at MOH level gives Armenia a stronger voice in working with PVOs than a decentralized process wherein each individual facility solicits drug donations. The minister also said that the director of HAO has been able to improve upon the results of the process,<sup>20</sup> that is, increase the supply of drug donations obtained, while keeping down the cost of soliciting them.

The minister favored the centralized process, because the director of HAO and the head of ADMTA are better able to avoid the impulse to accept all donations in the context of Armenia's limited capacity to purchase drugs. Instead, they focus on the need of the country to carefully accept only those drugs that are longer dated and most appropriate. The administrators and pharmacists who were interviewed said that without donated drugs, their drug supply would be inadequate, and HAO "does its best to get useful drugs donated."<sup>21</sup>

The centralized process also assures lower costs of receiving donations. The healthcare providers and the MOH stated that the centralization of the donation process results in relatively lower costs for the country's healthcare system and a larger volume of free drugs for patients than any approach where the government is not the main conduit for donations. The director of HAO pointed to the efficiency of the process,<sup>22</sup> indicating that the centralized information about the patient mix at all institutions in Armenia helps him solicit appropriate drugs. The director also stated that he can respond much faster to offers from PVOs than 600 individual health facilities ever could. He can negotiate for transport from overseas to Armenia for all donations, including those he solicited and those from individuals or Partners. The next steps are also simpler, according to the director, if they are carried out for one large shipment rather than for many small shipments: clearing donated drugs through Customs, transporting them to the Republican Warehouse, conducting the inventory, allocating the drugs to health facilities, tracking products, and destroying drugs when they reach their expiration date.

Donors also benefit from this centralization, according to the minister of health, since they work with one Armenian counterpart, who in turn works with one or two sources of transport. For the PVO, this is a streamlined process, designed to move large blocks of donations faster than is possible in a decentralized system where each healthcare provider sets up a separate office for soliciting products.<sup>23</sup>

The centralized process helps to simplify the logistics of obtaining drugs. According to the director of HAO, the centralized nature of the Armenian drug donation process gives him unique information on the use of donated drugs in Armenia. The centralized donation process will allow detailed tracking of donations and stocks, once the donation data are computerized. Although that data set is not now currently available for analysis of distribution or utilization patterns, the director maintained that the current logistics of the process are much more efficient for healthcare providers.<sup>24</sup>

Finally, the centralized process helps to promote equity. Those interviewed at MOH felt that the highly centralized donation process allows an equitable way of soliciting, allocating, and distributing drug donations.<sup>25</sup>

Health facility managers also stated in interviews their belief that, in comparison with a decentralized process, the process is “fairer” to all facilities if it is coordinated by the government. In a decentralized system where each facility solicits donations directly, administrators and pharmacists with better access to donors have an advantage. The result may be an inappropriate allocation of drugs that does not take into account equity among health facilities and among patients.

### *Donated free drugs*

Donated drugs help poor patients maintain access. Free drugs are very important in a country where, according to the interviewed healthcare providers, the majority of the population have insufficient income to pay out-of-pocket for drugs. Both the healthcare managers and the government reported finding donations a helpful way to provide equitable access to drugs for patients. Because most of their patients do not have any funds, healthcare professionals were concerned about sending patients to purchase drugs from pharmacies outside of the hospital when the health facility runs out of donated or purchased drugs. Facilities are particularly concerned about patients who have no friends and family who can help out as articulated by an interviewee at Children’s Hospital:

*One of our patients is a 10-day-old baby from Nagorno-Karabakh with severe sepsis, osteomyelitis, multiple abscesses and a low protein level. The child needs two types of antibiotics and a protein solution. If we did not have donated products, we could not help this baby.*

Healthcare providers stated in interviews that unless free donated drugs are available, patients often have to borrow money from relatives and friends, then cut back on their food or heating so they can pay back what they borrowed.

Donated drugs save resources in the government budget for use elsewhere. It is difficult for HAO, without a computerized data base, to estimate the amount of resources made available by donated drugs, but its director stated that the healthcare system would not function without donated drugs.<sup>26</sup>

### *Direct solicitations by health facilities*

The Armenian donation process allows facilities to solicit drug donations on their own, and to have these shipped to Armenia via cargo flights organized by MOH with its overseas partner PVOs. Direct solicitations are a source for specific, scarce, and expensive drugs. Sometimes direct solicitations by professionals can result in the donation of drugs that are not commonly donated, such as drugs to treat patients with tuberculosis, diabetes, and kidney transplants. According to the interviews, being able to solicit these donations directly is perceived as helpful by healthcare professionals and managers of facilities.<sup>27</sup>

Direct solicitations are also not subject to import duties or government charges. Currently no import duties are levied on donated drugs, and there is no government charge to facilities that obtain donations on their own.

As noted previously, direct solicitations may provide additional resources to the facility. For example, drug donations are sometimes exchanged for other drugs with other facilities or with private pharmacies.<sup>28</sup>

### *Perceived drawbacks*

#### *Drug donations insufficient*

The types and volume of donated drugs are unpredictable. The most difficult logistical issues for health facility managers are the unpredictability of the types of donated drugs, their widely fluctuating quantities, and their sporadic arrival. Even though the process has been centralized by HAO, the current donation process does not guarantee a stable supply of drugs. In a country where healthcare providers rely very heavily on donated drugs, this unpredictability creates serious organizational difficulties for doctors, nurses, and pharmacists. The fact that all pharmacy information is non-computerized adds to the logistical difficulties in planning for a stable supply of drugs and in spending the limited available funds on drugs to supplement donations.<sup>29</sup>

Respondents indicated that they could cope with short-dated drugs if donations were shipped routinely and predictably. If, however, they do not know when the next shipment of drugs will arrive, they cannot decide whether to use the short-dated drugs quickly or to hoard them in

case no other drugs arrive in time. This situation leads to drugs not being used where they are most needed, as well as to expired drugs being used.<sup>30</sup>

Sometimes, the type and volume of donated drugs do not meet current needs. One example of a product that did not meet the recipients' need was observed in each of the facilities visited: large quantities of a fixed-dose combination of an analgesic and a decongestant (ibuprofen 200 mg, pseudoephedrine 30 mg). Unpacked boxes of the product were observed, stacked on floors and on the top of shelves up to the ceilings. In a timespan of two months in the fall of 1995, Armenia received over 140,000 packages of 20 tablets each of the drug, with an expiration date of 10/97, from two PVOs. HAO then distributed these drugs to the health facilities. The pharmacists and physicians used this combination drug for its ibuprofen content, because no alternative was available. Every health facility pharmacist who was interviewed told us that with no alternatives, that is what they would use. Each would have preferred a drug containing only ibuprofen.

The logistics of drug management are very difficult and some waste occurs. The logistics of using donated drugs is difficult for health facilities because the variable nature of the incoming drug supplies adds to the difficulties of purchasing, inventorying, and prescribing. Pharmacists reported having to instruct other medical staff regularly on the usage of incoming drugs.<sup>31</sup> The quantities of donated drugs can also cause problems for medical staff, resulting in periods of overabundance, followed by periods of scarcity.<sup>32</sup>

Finally, there is insufficient data on donated drugs at the central and facility levels. The unpredictable nature of donations also creates logistical difficulties for MOH, which must balance drug need and supply. The director of HAO reported difficulties in predicting the supply of drugs from both donations and the private market. Allocating anticipated shipment of drugs to the various institutions, so as to minimize waste and optimize their usefulness, is another logistical problem without computerized inventories.

#### *Lack of input by health facilities*

Facilities have insufficient input into the solicitation process. Health facility managers responded that the input they are asked to give is not sufficient to obtain the drugs they need. An annual report on patient case mix and informal discussions on "desperately needed" products, they believe, does not provide sufficient information to HAO or the donors.

Facilities also have insufficient input into the allocation of donations. Health facility managers reported that they frequently have to redistrib-

ute the drug donations they receive from MOH among themselves. Hospitals may receive products they have little use for, and other facilities may wish to trade with them for drugs they need very much.

### *Lack of transparency*

On the one hand, the overseas process is not clear to healthcare managers. The health facility managers and pharmacists do not seem to fully understand either the logistics of the drug donation process in the countries of origin or the involvement of manufacturers, PVOs, and Diaspora PVOs. Believing that the Diaspora PVOs buy some or all of the products that are shipped to Armenia as humanitarian aid and assessing their share of these donations, they wonder how the product selection is made by the PVOs and HAO. The facility managers do not know that the director of HAO is limited in his ability to solicit donations and generally will only respond to offers of donations (that is, accept or reject part or all of them). The managers also do not know that he has no resources or power to obtain the exact quantities and delivery schedules of drugs that are needed. Because the healthcare providers do not understand the process, they are frustrated about not getting the drugs that are high on their priority lists.

On the other hand, the Armenian regulatory process is not clear to overseas Partners. Not all overseas Partners are familiar with the conditions in Armenia and with the logistical difficulties of running a health-care system using such a high proportion of donated drugs. Donors who have requested approval to ship short-dated products to Armenia have been disturbed when they did not receive a Customs certificate from the director of HAO. The director provided several exchanges of letters as examples of these situations.

In general, the director of HAO tries to discourage short-dated drug donations that might arrive only a few weeks prior to expiration. He is engaged in an effort to convince Armenian health facility managers as well as overseas Partners and PVOs, that he prefers longer expiration dates, unless Partners and PVOs can guarantee the arrival of the product in time for its appropriate use, and unless there is no alternative source.<sup>33</sup>

## **WHO *Guidelines for Drug Donations***

### **Knowledge of and reactions to the WHO *Guidelines***

Although Armenia has not developed its own drug donation guidelines, its National Drug Policy states that it will follow the WHO *Guidelines for Drug Donations*. In Armenia, ADMTA and HAO follow the WHO

*Guidelines* and its exceptions when reviewing each potential drug donation, including drug donations brought in by individuals. The head of ADMTA recalled several occasions in the past where drugs brought into the country by individuals did not contain the appropriate amount of the active ingredient or had expired. Customs officials now have been instructed not to admit drugs without permits from MOH.

The WHO *Guidelines* provide four general principles for donations and 12 guidelines (see Chapter 1 of this report). According to our interviews at MOH, the minister, the director of ADMTA, the director of HAO, and the director of the Republican Warehouse are very familiar with the WHO *Guidelines* and with the exceptions. The persons interviewed at health facilities, however, were not familiar with the *Guidelines*; to obtain their views, the interviewer provided a copy of them to respondents during the interview, then asked for their reactions.

Among the persons interviewed, there was general agreement that the core principles of the WHO *Guidelines* (maximum benefit to recipient; respect for wishes and authority of the recipient; no double standards in quality; effective communication between donor and recipient) are useful criteria for the Armenian drug donation process. Table 5.8 provides an overview of the knowledge of and reaction to the principles of the WHO *Guidelines*; a discussion of the interviewees' reactions to each of them follows.

TABLE 5.8

### Knowledge of and Reaction to Principles of the WHO *Guidelines*

Facility No. or Respondent	Knowledge of Guidelines	Guidelines Translated During Interview	Reaction to Principles
1	No	Yes	Positive
2	No	Yes	Positive
3	No	Yes	Positive
4	No	Yes	Positive
5	No	Yes	Positive
6	No	Yes	Positive
Minister	Yes	No	Positive
Director of HAO	Yes	No	Positive
Director of ADMTA	Yes	No	Positive
Director of warehouse	Yes	Yes	Positive

HAO = Office of Humanitarian Assistance.

ADMTA = Armenian Drug and Medical Technology Administration.

The director of HAO stated that the WHO *Guidelines* can be helpful in the management of the donation process if a country uses the exceptions listed therein in determining which offers of drug donations to accept. He has highlighted the exception paragraphs in his copy of the *Guidelines*, and he refers to them as needed in dealing with PVOs. The director of HAO reported that he does not differentiate between the bold print of each guideline and the normal print of the possible exceptions that follow each guideline.

For example, he indicated that he would apply the *Guidelines* to the offer of a drug with three months of shelf life at arrival as follows: If it meets Armenia's expressed need, can be used in that time, and there is no alternative, then it will get approval by HAO. If there are alternatives, then he would not consider it as meeting a need. He therefore suggested that the exceptions be incorporated into each guideline.

The Office of ADMTA wanted to apply the WHO *Guidelines* more rigorously. The director of this office has been advocating the enforcement of a one-year expiration date requirement, a ban on combination drugs, and a requirement to use only generics. During the interview for this study, he said that he would consider a six-month expiration date the absolute minimum.

Table 5.9 lists the 12 WHO *Guidelines* and the overall perceptions of individuals who were interviewed at MOH and the health facilities.

### ***Guidelines perceived as advantageous by ministry officials and facility managers***

*Guideline No. 1:* All drug donations should be based on expressed need and drugs should not be sent without prior consent by the recipient. *Reason:* That is how they currently operate. MOH officials stressed that it is important to be partners with donors.

*Guideline No. 5:* No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere. *Reason:* These types of donations are perceived as too risky, because nothing is known about the conditions under which they have been stored. Armenia had a very negative experience with returned prescriptions that came from Europe during the response to the 1988 earthquake. Those interviewed did not report receiving such donations from the United States.

*Guideline No. 10:* Recipients should be informed of all drug donations that are being considered, prepared, or actually underway. *Reason:* To optimize the use of products and to be able to plan ahead, it is necessary

T A B L E 5 . 9

**Perception of Guidelines by Facilities**

**Guidelines perceived as advantageous:**

1. Expressed need/prior consent
- 5a. No returned drugs
10. Advance notice
12. No transportation charges, unless first discussed

**Guidelines perceived as disadvantageous or irrelevant\*:**

2. On EDL, approved for use in country
3. Formulation as in Armenia
4. WHO certific scheme
- 5b. No physician samples
6. Shelf life > 12 months
7. Language, INN, expiration date
8. Larger quantity units/ hospital packs
9. Packing list, weight, mixed mailing
11. Declared at generic value

\* These guidelines were considered too difficult to implement, could lead to reduced shipments, or should be decided by the recipient.

to be able to decide whether to accept a product and to know when it will arrive. This is how they currently operate.

*Guideline No. 12:* Costs of international and local transport, warehousing, port clearance, and appropriate storage and handling should be paid by the donor agency unless specifically agreed otherwise with the recipient in advance. *Reason:* This approach is what they are used to. It would be difficult for them to raise funds for the high-cost air cargo shipments needed to bring donations to Armenia.

***Guidelines perceived as disadvantageous by ministry officials and facility managers***

*Guideline No. 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. *Reason:* The selection of drugs should be up to the Armenian government and health facilities, but this guideline would exclude impor-

tant new products. Highly educated professionals at MOH are able to assess whether a drug is a reasonable equivalent. If a donor used solely the WHO *Guidelines* and the Armenia EDL to decide whether to send a drug, the donor might not make the drug available for donation. This consideration is particularly important for new drugs, but it may also be important for products such as cough syrup, which is being requested by Armenia.

The Armenian National Drug Policy includes two paragraphs that would further limit what can be donated: a section on brand names and one on fixed-dose combinations of drugs. Brand names are discussed as follows:

*Drugs for the public sector health facilities shall be procured using the International Non-proprietary Names (INN). The Ministry of Health will encourage marketing of drugs by generic names. However, if any drug is marketed by brand name, its generic name should be prominently printed on the label. In all health facilities, drugs should be prescribed by generic names.*

The majority of donated drugs observed were brand-name drugs. The pharmacist in Facility No. 1 expressed the sentiment of the respondents in facilities:

*The patients prefer small, original manufacturers' packages. They recognize the brands. The packages are classier. Our patients are not used to having pills dispensed from large bottles into brown paper bags. We understand that generics and hospital size bottles would be cheaper to ship. It might be O.K., if we could get a full supply of the needed drugs regularly.*

The director of HAO felt that the country can afford to enforce this rule only on generic names for purchased drugs, not on those for donated drugs.

The Ministry of Health made the following statement on fixed-dose combinations:

*Fixed dose combinations will be discouraged. Only those with proven advantages such as increased therapeutic effectiveness, low-cost and better compliance will be allowed to be marketed in the country.*

HAO felt that the need for donated drugs in the country outweighed the preference for single-ingredient drugs. Generally, the facility manag-

ers agreed that fixed-dose combination drugs could be used if no single ingredient drugs were available.

*Guideline No. 4:* 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. *Reason:* The respondents at MOH stated that requiring the WHO certification scheme would make donating drugs too difficult for US donors. Requiring US donors to get another certification would be asking for something that does not improve the quality of the donation; rather this requirement would simply cause extra cost and results in a time delay. As long as the product is registered in the United States with FDA certification and is handled by PVOs with wholesaler licenses, there is no need for the additional WHO certification.

*Guideline No. 5:* No drugs should be donated that...were given to health professionals as free samples. *Reason:* Those interviewed at MOH indicated that excluding these free samples would exclude some useful donations. HAO receives some samples from manufacturers and some from health professionals. As long as the volume is large enough, samples do not pose a problem (the Republican Warehouse and the health facilities stated that they cannot cope with small amounts of differing samples.)

*Guideline No. 6:* After arrival in the recipient country, all donated drugs should have a remaining shelf life of at least one-year. *Reason:* Requiring a one-year expiration date on arrival for donated drugs excludes too many donations. Evaluating the drug donations the facilities currently receive, interviewees estimated that about one-third of products have an expiration date over one year. The administrators of the health facilities believe that they cannot operate effectively with just 33 percent of the current volume of donations.

An option suggested by MOH as being more reasonable is requiring six months prior to expiration. They felt it was most reasonable to leave it up to the recipient to accept or refuse, on a drug-by-drug basis. The officials did stress, however, that there should be a means of making sure that there is no penalty imposed by the donor for a facility's refusal of a donation. Several respondents stated that even drugs with three months of shelf life can be used if the quantity is small, and the shipment is regular.

The Office for Humanitarian Aid agreed with these healthcare providers. It favors a flexible cut-off point, depending on the need for the

product, the quantity offered, and the quantity on hand. Because the donation process is managed by HAO, everyone in MOH interviewed in this study (with the exception of the head of ADMTA) agreed that a 12-month cut-off point is not necessary, would be counterproductive, and would reduce donations. The head of ADMTA, however, favored a 12-month cut-off point, citing safety issues. After discussing the issue with the director of the Office of Humanitarian Aid, the head of ADMTA conceded that there should to be a fixed cut-off point of at least six months without exceptions.

***Guidelines considered not critical, not possible, irrelevant, or to be decided by the recipient***

*Guideline No. 3:* The presentation, strength, and formulation of the donated drugs should, as much as possible, be similar to those commonly used in the recipient country. *Reason:* It may not be possible to obtain drugs in the same strength and presentation in which they are commonly available in Armenia. This is not seen as a serious problem because professionals can usually understand alternative formulations of most drugs. The interviewees stated that, in the long run, the enforcement of this guideline would reduce logistical problems but could also reduce the amount of donated drugs: thus it could be counterproductive if stringently applied.

*Guideline No. 7:* All drugs should be labeled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Non-proprietary Name (INN, or generic name), batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions, and expiry date. *Reason:* Labeling of drug donations was not perceived as a problem. Armenia only rarely receives products labeled in languages that people there cannot read. Indeed, most products are labeled in English or other languages that health professionals can read. Products from the United States usually have the necessary information on the label. The literacy rate in Armenia is 99 percent, with everyone speaking fluent Armenian and Russian and most medical personnel proficient in English. All pharmacists reported having PDRs available and being able to interpret names.

*Guideline No. 8:* As much as possible, donated drugs should be presented in larger quantity units and hospital packs. *Reason:* Requiring that drugs be donated in hospital-size packs could significantly reduce the volume of

donations, since donation shipments now contain only an estimated 10 percent in hospital-size packs. While the hospital-size bottles would be cheaper to ship and facilitate hospital dispensing, people in Armenia are reportedly used to the manufacturers' packages.

*Guideline No. 9:* All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which 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. *Reason:* MOH wants to request packing in a way consistent with how the donations will be used. Packing lists are always requested, but box size could vary, as could the requirements for other items in the box.

*Guideline No. 11:* In the recipient country the declared value of a drug donation should be based upon wholesale price of its generic equivalent. *Reason:* The declared value of a donation is irrelevant for Armenia, since Customs imposes no import duty, and the value of the drug for purposes of assessing the handling fee is currently determined by MOH independently of the donation's declared value.

### **Current and potential impacts of the WHO *Guidelines for Drug Donations***

According to interviewees, the current perceived impact of the application of the WHO *Guidelines for Drug Donations* differs by the channels through which the donations are being sought and received: Where MOH acts as broker and works directly with PVOs, the yield of the process of donations seems to be improving. The director of HAO is working with PVOs to increase the dating of drugs and to obtain drugs with the characteristics most needed in Armenia. According to the director, this has been more feasible since the regular monthly cargo flights began in spring of 1997. He believes that the current donations respond more to the needs of the country. While some short-dated or non-needed drugs are no longer being shipped, the overall volume of donations has not been reduced, and the selection of drugs has improved. (Because of the lack of an effective information system, the author could not obtain statistical data to support these statements obtained in interviews.)

For the small proportion of offered or received donations that are not accepted, including those directly solicited by health facilities, the direc-

tor of HAO quotes the WHO *Guidelines* to explain why they cannot be accepted. According to the director, these are rare occurrences, and the decision to refuse some donations has not had a noticeable impact on the overall quantity of donations. Individually hand-carried drug donations may, however, have diminished in volume. For example, the US Partner of one facility no longer brings drugs into the country.

Donations of funds to enable the Armenian providers to purchase drugs on the market or order specific drugs from a Partner in Germany or Canada, have not increased as a result of application of the WHO *Guidelines*.

The future impact of the continuing application of the WHO *Guidelines* was seen as depending on how the exceptions to them are used and on the availability of tax revenues in Armenia to fund healthcare. The minister of health said that he will have HAO continue to coordinate and broker donations until Armenia no longer experiences an extreme shortage of funds and of drugs.

## Conclusions and Recommendations

Overall, this survey found that Armenia has a relatively well-organized drug donation process that results in substantial pharmaceutical donations to its facilities and healthcare providers. Healthcare professionals, however, experience some difficulties with the logistics of the process that should be addressed. The donation process also could be improved by increased involvement of health facility recipients in the centralized process, by greater transparency, and by increased levels of information. Based on the information collected during this field study, we suggest three main areas in need of improvement:

1. *Logistics:* All parties involved in the drug donation process should continue to improve the logistics of the process, with the goal of producing more routine and predictable shipments.
2. *Transparency:* All parties involved in the drug donation process should improve the transparency of the process by involving end-user recipients (health facilities) in the donation process and by providing information (to health facility managers) about the objectives, policies, and procedures of PVOs and drug manufacturers who donate products.
3. *Information:* All parties involved in the drug donation process should improve the data base for tracking drug donations to improve the management of available donated drug stocks, to regularly identify

drugs that are needed, and to facilitate requests by and distribution to recipients at healthcare facilities.

## Endnotes

- 1 Armenian Public Health Association, Health Regions, 1997 map.
- 2 The International Bank for Reconstruction and Development/World Bank, *World Development Report* (New York, 1996), pp. 184–222.
- 3 Armenian Public Health Association, 1997 map.
- 4 “We realized in the 1988 earthquake that if we have no systematic policy, drugs will be donated and arrive that are not needed. During the earthquake, and even afterwards, only 30 percent of the donations met our needs, because a large proportion were for chronic diseases, not emergency supplies for the earthquake, and the remainder of the drugs were expired.” The former minister of health, currently the director of the Armenian Drug and Medical Technology Administration.
- 5 The International Bank for Reconstruction and Development/World Bank, *World Development Report* (New York, 1997), pp. 124–125.
- 6 The private voluntary organization referred to in this report are those in the United States which collect donations of drugs and medical supplies and equipment and make them available to healthcare facilities that have a specific need for these supplies.
- 7 Diaspora PVOs are defined in this report as those international PVOs that provide humanitarian assistance solely to Armenia. These organizations are typically comprised of people of Armenian descent residing outside of Armenia.
- 8 The *Physicians’ Desk Reference* (PDR) is a US–published reference guide that lists drug descriptions, indications, and contraindications of all FDA-approved drugs.
- 9 “Republican” refers to the “Republic of Armenia,” similar to how the term “federal” refers to functions of the federal government as distinguished from “state” functions in the United States.
- 10 The Ministry of Health of the Republic of Armenia, The Armenian Drug and Medical Technology Administration. The World Health Organization, *National Drug Policy in the Republic of Armenia*, Report from a consultative meeting, Yerevan 2–5 October, 1995.
- 11 ADMTA, Essential Drugs List for Republic of Armenia (Yerevan: 1995 and Yerevan: 1997).
- 12 World Health Organization, et al., *Guidelines for Drug Donations*, WHO/DAP/96.2, May 1996. (Other authors: Office of the United Nations High Commissioner for Refugees, United Nations Children’s Fund, International Committee of the Red Cross, International Federation of Red Cross and Red Crescent Societies, Médecins sans Frontières, Churches’ Action for Health of the World Council of Churches, and Oxfam).
- 13 World Health Organization, Essential Drugs (WHO Model List, revised in December 1995). See *WHO Drug Information* 1995; 9(4): 223–234.
- 14 A written communication received after the field survey from another official in the Ministry of Health estimates donated drugs to constitute 50 to 60 percent of all drugs used in the country (that is, prescribed and over-the-counter drugs, in the public and in the private markets combined). None the less, the more conservative number of 30 to 40 percent is used throughout this report, since it was obtained during the field visit.
- 15 In order to ensure the appropriate handling of drug donations, the plane is accompanied by an employee of the Charter company who supervises loading and unloading. A representative of the Armenian PVO flies along on every supply flight it sponsors to assure oversight and delivery.

- 16 HAO is perceived as a source of drugs by the hospitals.
- 17 Hospital No. 3 and polyclinic No. 4 reported having no outside personal contacts for obtaining drugs but receiving donations of short-dated, overstock, or unneeded drugs from larger hospitals.
- 18 All tracking of drug stocks is done manually; no computerization is expected within the next year. Donated drugs are usually recorded separately from the purchased drugs, and they are also stored separately from purchased drugs. A reason for this separate storage could not be elicited from the respondents.
- 19 *There is a huge need for active tuberculosis treatment, but we really got involved by circumstance. One of the consultants involved in our US AID-financed "Post Graduate Skill Building Program" was particularly interested in tuberculosis. People in the US like to volunteer, and he decided to solicit drugs for the trauma hospital. Now that he is no longer working with us, we no longer have the access to tuberculosis drugs.*  
*Insulin was specifically requested by the trauma center. When we first worked on the Skill Building Program, we decided in the US what drugs and other supplies to bring to Armenia. Apart from looking at the need of our Partner in Armenia, our "donations" were selected by what we could easily obtain from our vendors as donations, or from our hospital overstock and short-dated drug supply. However, we quickly changed to focus on the Armenians' requests, rather than have us judge their needs.*  
*Between '93 and '94 it was easy to hand-carry drugs to Armenia. In 1995 we experienced serious difficulties with Customs at Yerevan Airport. Because of these difficulties, and because we do not have easy access to donated drugs, we did not donate any drugs in 1996 and 1997. It simply was too much of a hassle. We have continued to ship boxes of supplies, but no drugs, via the airlift sponsored by the US-Armenian PVO. (Interview with US Partner of Hospital No. 1)*
- 20 The minister of health described the 1988 earthquake experience in an interview conducted for this study: "We received humanitarian aid, but mainly what the donors wanted to provide us with, not what we needed. With difficulty we worked this out and we succeeded in collaborating with the donors to bring into the country what was needed."
- 21 *Many donated drugs are desperately needed. Without donated drugs we cannot serve patients. (Facility No. 4) Without donated drugs we could not function. (Facility No. 2)*
- 22 *The process is low cost. There is no import duty on donations. The individual facilities invest little money and little time on the front end of the process. We consolidate expensive phone, fax, or express mail contacts with overseas donors or PVOs at the ministry level, rather than at the level of the individual facility. (The director of humanitarian assistance)*
- 23 *Donors like to work with such an efficient system. (PVO representative accompanying the May 1997 cargo flight)*
- 24 *Once a year facilities submit a report with the facility's patient mix, and a "wish" list of drugs. The next responsibility of the facilities is to pick up the donations at the Republican Warehouse of Humanitarian Assistance, and to keep track of their use. (The director of humanitarian assistance)*
- 25 *The government distributes all humanitarian assistance. MOH was against a decentralized direct program between the foreign countries and the hospitals, because only the government is able to distribute donations equitably. (minister of health)*
- 26 *Government has insufficient funds for salaries and capital equipment. Without donated drugs we would have no drugs. (The director of humanitarian assistance)*
- 27 *Last year government paid only the salaries of the hospital. Our Canadian Partner will send us drugs this June. We write them what type of drugs we need, and they send them to us. For example we asked for antibiotics, analgesics, drugs for heart disease, and supplies for OB-GYN. (Facility No. 2)*

- 28 *We hardly ever refuse donations. In 1994 we received a shipment from our partner, and we exchanged drugs we did not need (10% of the shipment) for other drugs in private pharmacies.* (Facility No. 2)
- 29 *It is difficult to predict stocks when the office of humanitarian assistance gets humanitarian aid from many channels. It would be much easier for us to start purchasing drugs again from Syria and Egypt, if we had the money.* (Facility No. 6)
- 30 *We used to get drugs with two to three days shelf life, and others with over two years. Last year I personally used expired drugs (where the shelf life had run out six to 12 months before), because that was what we had left.* (Facility No. 6)
- 31 *Yes, we receive a great variety of drugs. But we know how to manage. We have current PDRs, I am a registered pharmacist, I know my drugs, and I make up instruction sheets for the physicians on how to use a drug formulation they have not seen before. These I hand out at our weekly staff meetings, and then I post them for the physicians. As long as we get drugs, we can cope with different formulations, different language inserts.* (Facility No. 2)
- 32 *We receive a lot of analgesics all at the same time, not spaced out over time, and cannot always use such large amounts. Unless the polyclinics or other hospitals need them, we have to destroy them eventually. We hardly ever destroy any drugs, if we can avoid it.* (Facility No. 1)
- 33 *It is important not to provide a permit for such short-dated products, even when they had been specifically requested, because it is critical to have donors realize that the continuing practice of sending short-dated product causes logistical difficulties in the hospitals and polyclinics.* (The director of humanitarian assistance)

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