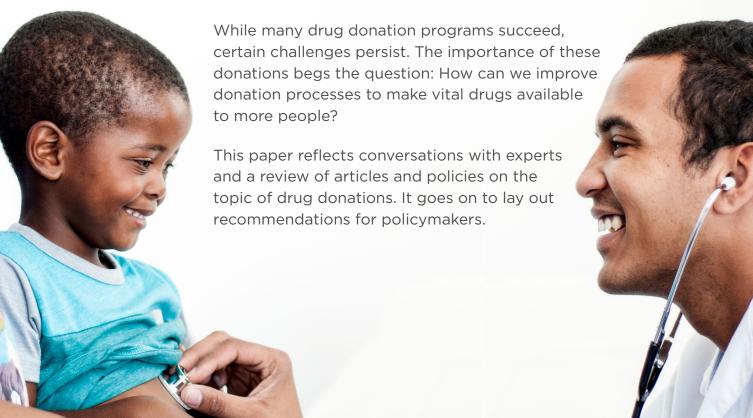


THE ROLE OF DRUG DONATIONS IN EXPANDING ACCESS TO

MEDICINES

INTRODUCTION

Millions of low-income people in countries and communities around the world depend upon the generosity of donated drugs. Over the past two decades, the appropriateness of donations—that is, how well donor offerings reflect actual need—has improved dramatically.^{1,2,3} Whether donated from surplus stock, through philanthropic contributions, as part of disaster responses, or through longer-term development programs, drug donations are critical to global health.



THE IMPACT OF DRUG DONATIONS

Drug donations can make treatment accessible for patients and communities in need. They also have a more far-reaching impact, such as strengthening health systems, securing sustainable supply chains, and fostering markets and public services that promote patient access. Drug donations to low- and middle-income countries in particular can free up funds that would otherwise have been spent purchasing drugs through third-party or local vendors at a higher price. These funds can instead support critical resources such as infrastructure, human resources, and capacity for health systems.

Donations can also indirectly enhance governance and accountability. Accepting donations requires, for example, additional reporting by receiving governments and institutions. In many instances, donation programs can encourage improvements in technology, management, and monitoring and evaluation. In short, donation programs may directly help patients while also providing wide-ranging benefit to local programs and systems.

Though drug donations are often seen as part of development aid or post-disasters response, they can also meet a specialized need, even in developed countries. A unique program in the United States, for example, accepts donated drugs from the public, and focuses on specialized, often costly, medications. Medicines to treat HIV/AIDS or cancer are typically donated through this program from patients or family members of patients who have succumbed to their illness.

A major concern and possible disincentive in the United States is the issue of liability, though The Cancer Drug Donation Program Act indemnifies all parties when individuals, hospitals, and other entities donate prescription cancer drugs to qualifying patients. These donations can have a powerful impact on patient access to certain specialized drugs.

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HOW DRUG DONATIONS WORK

Drug donations entail more than a patient community in need and a pharmaceutical company or entity willing to give. Health facilities receiving drug donations often rely on intermediate organizations, typically non-governmental organizations (NGOs), which have expertise in receiving and disbursing drug donations. These organizations may get the drugs directly as offers from pharmaceutical companies, or through collections and contributions from clinical facilities and health systems in donor countries. NGOs serve as the critical interface to understand and represent recipient need, and to assess the appropriateness of donor contribution.

Furthermore, these NGOs understand which donations are feasible, based on factors such as:

- Type of drug
- Quantity
- Donor reporting requirements
- Recipient entity
- Country regulation and process
- Facilities for distribution

Experts acknowledge the key role that NGOs play, particularly international NGOs with local offices or those collaborating with local NGOs. These serve as an important bridge between the groups donating drugs and the groups delivering services, and ultimately, the end recipient, the patients.

To fully understand how drug donations can serve patients in need, consider a case study of drug donation success: neglected tropical diseases.

CASE STUDY:

NEGLECTED TROPICAL DISEASES

Neglected tropical diseases are communicable diseases that prevail in tropical areas that may have poor sanitation infrastructure. Though many of the diseases are lesser known—hence "neglected"—their impact in some areas rivals that of malaria or tuberculosis.

International responses to these diseases provide a model for how drug donations can be effective and efficient—for both donor and recipient. Their success reveals several hallmarks of effective donation policy and programmatics:



Appropriateness. The programs operate at scale, and dedicated entities work to ensure a good match between the donor offering and recipient need.



Coordinated response. The programs have oversight from technical experts, managers, program implementers, government officials, and community representatives. Treatment is scheduled annually (or sometimes bi-annual), providing wide geographic coverage and access even for those in very remote locations.



Forecasting. Coordination allows for accurate forecasting of where and when drugs will be needed. Requests are then relayed formally to the donating drug companies through the country office of the World Health Organization.



"Make to Give." Drug companies manufacture quantities based on these requests, a process often called "make to give." Many have committed to support training and incidental costs including shipping and duties, when required.



Partnership. Pharmaceutical companies provide millions of dollars' worth of donations to treat neglected tropical disease. They have solidified their role as partners in the international effort to control and eliminate neglected tropical diseases by:

- » Aligning donation commitments to the substantive programmatic endpoints of disease control and elimination.
- » Sustaining and expanded their donations.

Overall, experts assess that this model of drug donation works well, in large part due to a single, overarching factor: **donations are part of a planned, programmed health effort.**

OBSTACLES TO EFFECTIVE DRUG DONATION

Not every drug donation effort is a success, however. In fact, there are many examples of where donations do not work. Challenges faced by less successful drug donation efforts can offer lessons for policymakers in their efforts to improve and encourage drug donations across the globe.

These challenges often resemble those faced by health programs' "paid for" drugs. These challenges have been well documented and classified in a recent analysis by Management Sciences for Health. ⁴ They include:

- The relevance of drugs to the context and health services
- The capacity of local workers to deliver drugs
- National registration and compliance issues
- Sorting, labeling and language
- · Expiration, spoiling and damage of medicines
- Supply chain management and continuity between national and state levels
- Taxes and tariffs
- Disposal costs of unusable donations.

These problems tend to be more acute and widespread during disaster and emergency responses. Compared to cases where donations are made as part of development aid, these scenarios do not allow for as much time and diligence for planning.

Feedback from international NGOs experienced in managing donations offers insight into these challenges. One NGO reported that it declines as much as two-thirds of drugs that are offered for donation. This was due predominantly to a short period before the drugs' expiration or to the drugs being too specialized.

The first challenge, short expiry, leaves little or no time for shipping and distribution. Not every drug will have an immediate use, and it may sit on a dispensary shelf for some time. The second challenge, drugs that are too specialized, presents the problem of matching donations with providers whose patients demonstrate need for the donated drug. Compounding these challenges is the ad hoc nature of many donations, particularly those spurred by excess inventory.

The World Health Organization, which offers guidelines on universally accepted principles on donations, acknowledges these challenges. It notes that "the number of different agencies involved in procuring drugs—including ministries of health, manufacturers and donor agencies—can render the process highly complex and vulnerable to inefficiency and waste." The World Health Organization further explains that, "Some drugs arrive unsorted and labelled in languages unknown to the professionals in the field. Expired drugs (at the time of their arrival) and drugs close to expiry still comprise a large proportion of donations…"



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WORLD HEALTH ORGANIZATION

OPPORTUNITIES FOR IMPROVEMENT

Using NGOs to Strengthen Drug Donation Efforts

NGOs represent an opportunity for strengthening the drug donation process so that donations match and meet the needs of patients.

For instance, many NGOs have extensive programming and strong networks of recipients at the country level. They can readily accept donated medicines. Furthermore, the NGOs have expertise in warehousing, stock control and supply chain management, which help to overcome logistical and administrative challenges. The intermediary NGO, therefore, can serve a critical role in channeling donations and overcoming the challenges detailed earlier.

As governments and international partners look to strengthen drug donation programs, NGOs can serve as the critical interface between patients and donors, coordinating through the collection point, raising awareness, and working to ensure drugs are accurately identified and repackaged. This model appears to work well when operated with clear delineations, such as a defined geographic area, through a specific network of providers, or for specific disease categories that require multiple drug classes and regimens, as with cancer and HIV/AIDS.

Policy Strategies

Delivery of donated drugs range from large, dedicated programs with clear objectives on the use of drugs, to specialized drugs that help close the gap on access to high-cost medication. Furthermore, they can address multiple policy objectives:

- Providing important cost savings to programs, particularly when donors pay duties and tariffs
- Enabling coordination between public spending and private contributions
- Increasing efficiency and better using expertise of in-country and NGO partners
- Promoting accountability and strengthening governance of programs.

Several opportunities exist for policymakers and stakeholders to increase the efficiency, appropriateness and impact – especially during disaster and emergency responses. First, IT tools and mobile devices could offer an efficient way to collect requests, assess need, and organize response. Similarly, an electronic donation marketplace could help coordination and promote appropriateness, efficiency, and expediency, further enhancing drug donations as a vehicle for patient access to medicines.

Several policy responses could also increase access to donated medicines. They include:



Donation incentives.

By creating incentives, governments can encourage individual, health facility and pharmaceutical company donations, thereby increasing both the diversity and the quantity of donated drugs.



Robust resource support.

Governments can provide resource support to NGOs that facilitate donations, encouraging improvements and efficiencies. They might also support innovation to develop tools and technologies that accelerate and expand drug donations.



Public awareness efforts.

Profiling drug donations as a successful public-private-partnership model can help to sustain development aid and encourage broader participation in drug donation programs.

These efforts can make strides toward getting more donated drugs into the hands of patients who need them.

SUMMARY

- Drug donation programs serve as a significant mechanism to promote access to effective treatments for patients in need.
- Drug donations are best used when they are based on accurate forecasting of need and are donated through dedicated programs and organizations.
- Donations cannot, however, be a complete replacement for a lack of health care provider infrastructure, dynamic market systems or incentives for innovation. Ensuring that there are enough health care professionals per capita is important for developing countries, as is the availability of staff to develop necessary infrastructure.
- Policymakers should consider drug donations in their health and development strategies. Policy guidance and tools will encourage donations to expand patient access to treatment.
- Donation incentives, resource support and public awareness efforts could help encourage greater participation in drug donation programs and improve the efficiency of existing programs.

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