



Assessment of Global Pharmaceutical Donations

Do Donations Help Public Health and How?

Michele Forzley, JD, MPH

Veronica Arroyave, MPH

Elizabeth Ziemba, JD, MPH

Panel 333.2: The Politics between Industry and
Public Policy:
The Good and the Bad of How Industry Impacts
Public Health



*“ Drug Donations
Are Not For
Amateurs ”*

Dr. Hans Hogerzeil, WHO



Introduction

- 1999 Assessment of US Pharmaceutical Donations
Players, Processes and Products – M. Reich
- History of medical products donations
- Agenda today
 - Primer on donations
 - Donors – vertical programs
 - Intermediary NGOs – horizontal programs
 - Recipients – disaster relief
 - Findings – Donations – Help or Hindrance ?
 - Recommendations



Global Donations

- 2005 PQMD members US\$ 4.3 billion
- 2000-2005 IFPMA Members US\$4.4 billion
- Global drug market – US\$640+ billion
- Donations are small per cent of national health expenditures on pharmaceuticals.



Primer on Donations

- ▶ What are donations
- ▶ Who donates
- ▶ Why do donors donate
- ▶ Basic kinds of donations types
- ▶ Donation process
- ▶ Relationship to CSR



Corporate Perspective

The corporate community is actively considering its commitment from the standpoint of global citizen, community partner, employer and employee, stakeholders and stockholders to engage, confront and alleviate the social ills that afflict our global community.



Why corporations give?

Supply Chain Management - Donations optimize management of stock within the distribution network, increase asset turnover and reduce inventory carrying costs. Donations maximize cancelled orders, surplus inventory, over runs and re-labeled products.

Employee retention - Product donations allow employees and shareholders to take pride in the positive role that their company plays in responding to the world's health needs. Employee and stockholder involvement make a happier, more productive workforce. A happy workforce means high employee retention and retention of intellectual capital.

Tax Benefit - Section 170(e)(3) of the Internal Revenue Code provides a deduction for contributions of inventory to a qualified 501(c)(3) not for profit organization that serves the ill, needy and infants.

PRESERVES the environment – Donating is part of a series of steps in GOING GREEN. Donating rather than destroying product can reduce disposal costs and environmental concerns.

Corporate Social Responsibility – Positive media attention enhances a company's corporate social responsibility profile.

Disaster Risk Management - Disaster Risk Management Plan. Donations assist companies in pre-planning a response via product donations, employee giving campaigns, matching gift programs and pre-selected nonprofit partners to carry out it's corporate social responsibility initiatives.



Types of Gift in Kind (GIK) programs

- Produce to give (PTG) or Planned Giving program
- Price adjustment programs
- Disease specific initiatives
- Donation of surplus inventory
- Employee Secondment/International Corporate Volunteering



Disease Specific Initiatives

Diflucan Partnership program: Assists developing countries in receiving drug donations to treat opportunistic infections related to HIV. Partners with governments and NGOs.

<http://www.diflucanpartnership.org>

International Trachoma initiative: Seeks to control trachoma through comprehensive national programs and donation of azithromycin. Strategy is adapted to local conditions.

<http://www.trachoma.org/>

Mectizan donation program: The MDP was established to provide medical, technical and administrative oversight of the donation of Mectizan. Community based in-country distribution. Long-term donor commitment.

<http://www.mectizan.org/>

Viramune donation program: The goal is to reduce the transmission of the AIDS virus from mother to child through donation of Viramune.

<http://www.pmtctdonations.org/en/welcome/Default.aspx>



Challenges to product donations

Dating & Restrictions

- Major stumbling block
- Shorter Dated Product offers
- Donor Restrictions
- Advance MOH approval
- In-Country Manager Approval

Competition & Consolidation

- More NGOs seeking donations

- # of manufacturers has decreased- acquisitions and mergers

Manufacturing Changes

- LIFESTYLE drugs- not essential medicines
- Generic companies manufacture what NGOs want, but donate less and with less dating (typically 6 months or less).
- Just in time manufacturing- means less surplus to donate

Strategic Programs

Among major pharmaceutical companies, disease-specific programs are becoming increasingly popular.



Challenges to Donations Helping Meet Public Health Objectives

- **In-country Distribution:** The key to any drug program, whether procured or donated, is effective in-country distribution
- **Sustainability:** Some drug programs require a sustainable and reliable supply. Drug donations should not undermine the sustainability of supply
- **Flexibility:** Some treatments are improving rapidly and in these cases recipients should have the flexibility to change to an improved treatment when it becomes available
- **Appropriate Drugs:** Drugs have to be relevant to the disease patterns and treatment protocols of the recipient countries
- **Drug Specific Quality Assurance:** Drug donations can have higher QA requirements than other donated goods.



Intermediate NGOs and Horizontal Programs

- IMA, Americares, MAP
- INGOs can be “seen” as industry -Eyes and ears for sure
- Compare to recipients – World Vision
- For a “service fee” and subsidized by donations
- Intermediate by
 - Soliciting
 - Aggregating
 - Logistics
 - Warehouse
 - Specialty programs
 - Travel packs
 - Emergency Medical Kits



Intermediate NGO

- Important role in soliciting from multiple donors
 - Developing deep & long term relationships
- Other functions – logistics
 - but not only for recipients – also for donors
- Serves public health needs for
 - central medical stores
 - public and private hospitals
 - aiding implementers to meet public health needs
- Subsidize some cases



“I”NGOs + Public Health Impact

- Transparency with recipients
- Reactive rather than strategic
- Do good rather than do well
- More coordination between recipients & donors to structure assortment of products
- Lack technical staff and information systems
- Improve procurement balance between purchase and donation



The Recipient's View

- Donations of Medicines During Emergencies:
- ↑ Number and severity of natural disasters
- ↑ Media Coverage
- ↑ In number and dollar value of donations
- ↑ Problems of dealing with drug donations
- Worst problem: Small consignments of unsorted drugs/MD samples from individuals, professionals and charities
- Belief that “anything is better than nothing”
- No or few disaster preparedness plans



The Recipient's View

Widespread noncompliance with WHO drug donation guidelines result in inappropriate and excessive donations to be stored, sorted, transported, coordinated and disposed just when resources are strained and communications limited.

Adverse effect on production and usage of local, generic drugs familiar to local medical professionals – impact on prescribing practices.

Distrust of pharma – Donating hard to sell or expired medicines to get tax rebate or promote image or develop brand recognition in new market.



The Recipient's View: Recommendations

PLAN: Create emergency disaster plan based on national drug policies including WHO donation guidelines. Have procedures in place in advance.

EDUCATE: Provide media with accurate information and requests for specific donations including cash or WHO emergency kits. Train local staff. Educate the public.

PARTNER: Maximize existing relationships/create new relationships to improve supply chain, logistics. Partner w/ experienced & respected groups.

REJECT: Just say No! to improper donations.

FEEDBACK: Learn from mistakes and report to donors what worked and what did not.

MONITOR & EVALUATE: make it part of every health program, including the drug donation component



Findings: Do Donations Help Public Health and How?

Even in the best of circumstances, governments and NGOs alone cannot deliver all help needed in the developing country context.

Donations are integrated into the missions and work of NGOs and represent a significant portion of NGO revenue.

According to the WhiteHouse report post Katrina, “NGOs play a fundamental role in response and recovery efforts and will contribute in ways that are, in many cases, more efficient and effective than the Federal government’s response. We must plan for their participation and treat them as valued and necessary partners (<http://www.whitehouse.gov/reports/katrina-lessons-learned/chapter5.html>).

“I” NGOs Little to No direct benefit – limited part of drug supply chain.

Insufficient evidence



What the GIK future holds?

- Public-Private partnership is an opportunity to strengthen collective focus on the full diversity of social ills facing society, non-profit governance and accountability.
- Build in-country capacity-donation availability at point of manufacture
- Enhance integration of GIK into NGO programmatic efforts
- Greater integrated Total Health approaches
- Enhance greater alignment of pharmco giving with program needs in field



WHO Guidelines

Largely G to G

Expand from the perspective of each player

Add vaccines, biologics, products for chronic diseases



Recommendations

For Donors

For Intermediate NGOs

For Recipients

For Governments

For Future Study

More Research

Development of How to Tools – Practical Guides
for governments and other players



Contact Information

For questions or information, please contact:

Michele Forzley, JD, MPH

Forzley & Associates

Global Public Health Lawyers & Consultants

301-565-0680

mforzley@comcast.net

Thank you for joining our session!



Presenter Information

- **Veronica Arroyave**, MPH, is a Ph.D. student @ VT School of Public & International Affairs, consultant and past Director of Corporate Relations & Medical Procurement for MAP Int'l. varroya@yahoo.com
- **Michele Forzley**, JD, MPH is Director of Forzley & Associates, Global Public Health Lawyers and Consultants and past Director of Philanthropic Investments for MAP Int'l. mforzley@comcast.net
- **Elizabeth Ziemba**, JD, MPH, is President of SHARED, a not for profit organization dedicated to improving access to essential medicines in developing countries. eziemba@healthshares.org



References

- An Assessment of U.S. Pharmaceutical Donations: Players, Processes and Products, Edited by Michael R. Reich, Harvard School of Public Health, Boston, MA 1999
- Guilloux A, Moon S, Hidden Price Tags: Disease-Specific Drug Donations: Costs and Alternatives, Medecins San Frontieres, October 2000.
- The Expectations, The Reality and The Burden of Drug Donation, Ministry of Healthcare and Nutrition, Sri Lanka, www.health.gov.lk/msd_publication.html, accessed October 2007.
- Getting the Best from Drug Donations, Essential Drugs Monitor, No. 21 (1996)
- Hechmann R, Bunde-Birouste A, Introduction: Drug Donations In Emergencies, Journal of Humanitarian Assistance, 26 September 2007, <http://jha.ac/2007/09/26/drug-donations-in-emergencies-the-sri-lankan-post-tsunami-experience>, accessed 8 October 2007.
- Study on Drug Donations in the Province of Aceh in Indonesia, Pharmaciens Sans Frontieres Comite International
- Currie R, Pust R, Pragmatic principles of pharmaceutical donation, Virtual Mentor, American Medical Association Journal of Ethics, December 2006, Vol. 8, Number 12: 801-807. <http://virtualmentor.ama-assn.org/2006/12/ccas1-0612.html>, accessed 8 October 2007
- Thomas A, Fritz L, Disaster Relief Inc., Harvard Business Review, November 2006