Research Synthesis: Donations

v1.0 researched and written by Elise Erickson, edited by Suerie Moon, last updated June 2018

Introduction

The literature on drug donations is thin*, especially with regards to non-emergency contexts and sustainability. Additional research seems to appear around revisions of the WHO’s ‘Guidelines for Drug Donations’ (revisions published in 1999 and 2010), but has been scarce since 2011/2012.

Search terms

Pharmaceutical/medicine/drug and donations

Synthesis of the literature

The WHO Guidelines for Medicine Donations (revised in 2010) is a key document (World Health Organization (WHO) 2011).

There are a handful papers that examine the extent to which donations comply with these WHO guidelines (Benaragam and Fernandopulle 2010; Bero et al. 2010; Dijk, Dinant, and Jacobs 2011; Reich et al. 1999), and others that document inappropriate donations pre-WHO guidelines (Berckmans et al. 1997). There is evidence that despite guidelines, many donations continue to be inappropriate (e.g. expired, unannounced, unsorted, or not registered in the recipient country). Cañigueral-Vila et al. (2015) propose both content and format modifications for the next edition of the guidelines.

There are a few studies that describe specific donation programs (Shretta et al. 2000, 2001; Thylefors, Alleman, and Twum-Danso 2008). Descriptions of Merck’s Mectizan donation program received a fair amount of attention as it has been running since 1987 (Thylefors, Alleman, and Twum-Danso 2008; Thylefors 2008; Samsky 2012; Collins 2004).

There appear to be more studies on drug donations in post-emergency settings (Berckmans et al. 1997) rather than non-emergency settings. Only a few papers examine questions of sustainability (including access or price) associated with donations in a non-emergency context (Guilloux and Moon 2000; Pérez-Casas, Herranz, and Ford 2001; Rustomjee and Zumla 2015). Access concerns are also sometimes found in commentary pieces (Smith 2017). Others argue that donations should be scaled-up, and that they are an appropriate answer to access issues such as medicine shortages and concerns with the impact of intellectual property rules (Tzeneva 2014).
Research gaps

- Impact of drug donations on medicines access, prices and on generics industry
- Sustainability of donation programs, especially in non-emergency settings and for diseases with long-term treatment periods (e.g. HIV/AIDS, TB, etc.)
- Tracking of product donation history of different pharmaceutical companies over time (in emergency and non-emergency contexts)
- Better understanding of tax benefits for pharmaceutical companies that make donations

Cited papers with abstracts


Abstract: The objective of this study was to describe the profile of the donated medicines, and to determine appropriateness and the extent of compliance with the WHO guideline. The survey was carried out from March 2005 to July 2005 and included mainly donations received and handled by the Medical Supplies Division, Ministry of Health. The data was collected using a set of investigator administered questionnaires from the Medical Supplies Division, and from the administrators, pharmacists, stores managers in hospitals and refugees in camps from the tsunami affected areas. A product that had the same drug substance, in the same dosage form and in the same strength irrespective of their brand name and package size was classified as a ‘Unique drug product’ (UDP). To determine compliance with the World Health Organisation (WHO) Good Donation Practices guideline, the 2003 version of the WHO Essential Medicines List, the Ministry of Health expressed list of needed drugs and the Sri Lanka Hospital Formulary List of Medicines were used. Useless drugs included medicines irrelevant to the epidemiological context or unregistered drug substances. Unusable drugs comprised medicines already expired on arrival or expired within a month of arrival, and unidentifiable drugs (labelled in unknown foreign languages / no labels). Appropriateness was also checked by comparing items with the WHO list of essential medicines in emergency situations.

Results: The majority of the UDPs (≈ 80%) were unsolicited, and arrived unannounced and in unsorted boxes. Around 50% of the donations were inappropriate collections of unused drugs from private individuals collected at various centres and transported via international relief organizations. These donations were a mixture of many different products mixed with other relief items. Fifty three percent of UDPs belonged to the ‘non list’ category (not listed in the MOH list, WHO – ML, HFL, WHO Emergency Medicines List) and 38% of the drug substances were never registered for use in the country.

Link: http://apps.who.int/medicinedocs/en/d/Js17523en/

Abstract: Not available.


Abstract:

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

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

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

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


Abstract: Some humanitarian and development organizations respond to major natural disasters and emergencies by donating medicines. Many provide medicines on a routine basis to support health systems, particularly those run by Faith-Based Organizations. Although such donations can provide essential medicines to populations in great need, inappropriate
donations also take place, with burdensome consequences. The World Health Organization (WHO) has developed the interagency Guidelines for Medicine Donations for use by donors and recipients in the context of emergency aid and international development assistance. Although comprehensive in nature and transferable to various emergency situations, adjustments to both content and formatting would improve this resource. Recommendations for the next version of these guidelines include: specific wording and consistent formatting; definition of who is a recipient, clear distinction between acute and long-term emergencies, and proper donation procedures pertaining to each; inclusion of visual aides such as flowcharts, checklists, and photos; and improving the citations system.

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4628229/


Abstract: A unique public/private partnership situated around a pharmaceutical, Merck's Mectizan donation program stands out as an example of corporate philanthropy in the history of the pharmaceutical industry and provides insight into future public/private partnerships in public health. This paper considers the issues Merck faced in the decision to donate Mectizan (ivermectin) and in the subsequent development of the Mectizan donation program, delineating the moral and financial debates that arose within the company. Coming after almost 15 years of donation, this assessment of the program's strengths and shortcomings suggests how the pharmaceutical industry can better serve as a viable partner in improving international health.

Link: https://www.ncbi.nlm.nih.gov/pubmed/15061171


Abstract: CONTEXT: Drug donations to developing countries may be part of medical relief operations in acute emergencies, development aid in non-emergency situations, or a corporate donations programme. After a number of documented inappropriate drug donations, the World Health Organization developed the 'Guidelines for Drug Donations', with the second and final version published in 1999. Objectives: We reviewed the medical literature on drug donations since the Guidelines publication in 1999.

DESIGN: Literature was retrieved from PubMed and other on-line databases as well as from relevant websites providing medical literature for use in developing countries. We considered the following donations to be inappropriate: (i) essential drugs in excessive quantities; (ii) mixed unused drugs (unsorted medicines and free samples); and (iii) drug dumping (large quantities of useless medicines).

RESULTS: We retrieved 25 publications dated after 1999, including 20 and 5 from the scientific literature and 'grey' literature (technical reports, working papers), respectively. New information concerned emergencies in East Timor, Mozambique, El Salvador, Gujarat State (India), Aceh (Indonesia) and Sri Lanka. Except for East Timor and Gujarat, inappropriate donations still
occurred, accounting for 85%, 37%, 70% and 80% of donations in Mozambique, El Salvador, Aceh and Sri Lanka, respectively. Very little information was found on drug donations in non-emergency situations.

CONCLUSION: There are few recent reports on the compliance of drug donations with the World Health Organization guidelines. For emergency situations, there is still room for improvement. Drug donations in non-emergency situations need to be evaluated. A reform of drug donations policy is needed.

Link: http://www.educationforhealth.net/article.asp?issn=1357-6283;year=2011;volume=24;issue=2;spage=462;epage=462;aulast=van


Abstract: One-third of the world’s population lacks access to essential drugs, often because of cost. These drugs could prevent or treat many of the communicable diseases that are killing 14 million people each year. As a response, some multinational pharmaceutical companies have initiated drug donations to combat specific diseases. Yet in its experience, Médecins Sans Frontières has witnessed serious drawbacks and problems with these donation programs. This paper examines the costs borne by the donor countries for drug donations. It also examines after-tax gains to the donor company and the impacts of tax incentives. The donation model is also compared with other models that can improve access to essential medicines, including the purchase of generics, concessionary pricing, discounted pricing, and differential pricing. The data show that drug donations can cost the public sector of a donor country (in this case, the United States) more than four times as much as other models that achieve the same end result; these models are to purchase either the lowest-priced quality generic on the world market, or the branded drug at a differential price. The data also show that the donor company does not have an incentive to lower its prices to a level affordable to the developing world, although its real manufacturing costs may allow it. The current system of incentives encourages drug donations over better policy options that would be more sustainable and less costly to the public. These other options also offer support to the generic industry and greater autonomy to developing countries in meeting their drug needs. In light of the numerous drawbacks to drug donations, they should neither be relied upon nor portrayed as a long-term solution to the ongoing crisis of access to essential medicines. National governments, NGOs, and intergovernmental organisations including the WHO, the World Bank, UNICEF, and UNAIDS, should promote solutions that are more sustainable than donations for the access crisis, such as encouraging generic production and negotiating dramatically reduced differential pricing for branded products. They should invest in the development of generic production and facilitate the use of TRIPS-compliant safeguards where appropriate. Finally, they should create a favorable policy framework that encourages differential pricing by proprietary pharmaceutical companies.

Link: https://www.researchgate.net/profile/Suerie_Moon/publication/242325532_Hidden_Price_Tags_Disease-Specific_Drug_Donations_Costs_and_Alternatives/links/0deec52eb0ecfe1aef000000.pdf

Abstract: Effective medicines exist to treat or alleviate many diseases which predominate in the developing world and cause high mortality and morbidity rates. Price should not be an obstacle preventing access to these medicines. Increasingly, drug donations have been established by drug companies, but these are often limited in time, place or use. Measures exist which are more sustainable and will have a greater positive impact on people’s health. Principally, these are encouraging generic competition; adopting into national legislation and implementing TRIPS safeguards to gain access to cheaper sources of drugs; differential pricing; creating high volume or high demand through global and regional procurement; and supporting the production of quality generic drugs by developing countries through voluntary licenses if needed, and facilitating technology transfer.


Abstract: This paper assesses the relevance and time-to-expiry of pharmaceutical donations by the USA by means of a convenience sample of two private voluntary organizations. Data were collected on 16,566 donations shipped between 1994 and 1997 for the two organizations to a total of 129 countries. For three field study countries (Armenia, Haiti, and the United Republic of Tanzania), between 37% and 65% of donated unique drug products were on the recipient countries’ essential drugs lists, and between 50% and 80% were either on these lists or were permissible therapeutic alternatives. Between 10% and 42% were not listed on either the national essential drugs lists or the WHO Model List of Essential Drugs, nor were they permissible therapeutic alternatives. For the worldwide data set, the median times to expiry when shipment by the organizations took place were 599 and 550 days; about 30% of shipment items had a year or less of shelf-life, and about 6% had less than 100 days of shelf-life. Although a majority of the donations fulfilled the criteria of relevance and time-to-expiry, a substantial proportion failed to do so. Actions are proposed with a view to improving the relevance and time-to-expiry of USA pharmaceutical donations.

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2557710/


Abstract: Tuberculosis (TB) remains a global emergency and is one of the most common infectious disease causes of death in developing countries. Current treatment regimens for multi-drug resistant TB are associated with low treatment success rates, are toxic, and require long duration of treatment. The need for shorter and more effective treatment regimens is urgent. Delamanid (Delt妳ba, or formerly known as OPC-67683) is a new dihydro-imidazooxazole
anti-TB drug active against resistant forms of pulmonary TB. Delamanid kills Mycobacterium tuberculosis by inhibiting the synthesis of mycolic acids required for cell wall synthesis. Whilst delamanid has been included in the WHO Model List of Essential Medicine by the World Health Organization Expert Committee on Selection and Use of Essential Medicines and in international guidance for the treatment of multi-drug resistant TB since April 2014, its access in countries with the greatest need, has proven challenging. This review provides an update on currently available clinical safety and efficacy data on delamanid and offers a discussion on research priorities and recommendations for expedited, expanded access.

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4631416/


Abstract: This essay sketches two international, pharmaceutical company–sponsored drug donation programs and assesses this novel integration of corporations into global health. Based on ethnographic interviews with retired and current pharmaceutical executives and scientists, international humanitarian workers, and volunteers and drug recipients in the Morogoro region of Tanzania, this essay develops a concept of “scientific sovereignty,” a process through which corporate and biomedical logics supplant the state in the exercise of biopower. I assess these interventions’ impact on a local health system and the theoretical implications of the global health orthodoxies on which they rely.


Abstract: Not available.

Link: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(00)02251-0/fulltext


Abstract: This paper describes the introduction of the Malarone® Donation Programme in Kenya. Using a policy analysis approach it illustrates the political nature of donation programmes and how they are affected by a large and varied group of national, regional and international stakeholders, with different levels of influence and experience. The paper shows that interaction between these different groups may affect the development and implementation of the donation programme. It ends by raising some more general questions about public/private partnerships and corporate donation programmes, and their potential impact on national drug policies.

Abstract: Not available.


Abstract: The launch of the Mectizan Donation Program (MDP) in 1987, by Merck & Co., Inc., created a number of new opportunities for onchocerciasis control. The macrofilaricide Mectizan was rapidly put to use by the Onchocerciasis Control Programme in West Africa (OCP), for mass treatment by field teams in selected areas. Other milestones in Mectizan treatment included the establishment, in 1992, of the Onchocerciasis Elimination Program for the Americas, and the creation of the African Programme for Onchocerciasis Control (APOC) in 1995, the latter programme covering all African countries in need outside of the OCP area. In 1998, the donation of Mectizan was expanded to include the treatment of lymphatic filariasis in those African countries where that disease is co-endemic with onchocerciasis. In the past, the development of a broad partnership around the MDP played a very important role, including non-governmental development organizations collaborating with the ministries of health in endemic countries. A new community-directed treatment strategy, which made it easier to reach out to all those in need, including those in remote areas, was developed by the APOC in collaboration with the World Health Organization’s Special Programme for Research and Training in Tropical Diseases (TDR). Several drug-management issues, including dosing, shelf-life, safety, and the reporting of severe adverse experiences, were addressed by the MDP, through its Mectizan Expert Committee, and by Merck & Co., Inc. A major research effort for the safe treatment of onchocerciasis in loiasis-endemic areas has also been supported by the MDP. Presently there are national programmes for Mectizan mass treatment in all 33 endemic countries in need of such treatment; >69 million Mectizan treatments for onchocerciasis were provided during 2006, and this number is expected to grow to at least 100 million treatments/year by 2010. This achievement has resulted in great public-health and socio-economic benefits for the populations concerned. Future challenges will include additional support to ‘fragile states’ resulting from conflicts or natural disasters, and the need for a strengthened primary healthcare (PHC) infrastructure. The community-directed treatment approach has been a great success but there is still a need to link the treatments to PHC, for the long-term sustainability of the treatments. The presence of loiasis in vast areas of Central Africa imposes a need for the mapping of that disease, and the application of safety precautions when distributing Mectizan in those areas. The recent decision to extend the APOC up to 2015 should facilitate the building of sustainable Mectizan treatment programmes that are integrated with the control of other neglected tropical diseases, such as lymphatic filariasis, intestinal helminths and trachoma. It will be important to define the safe end-point for Mectizan treatment in various settings, and an ongoing study by TDR will address this issue. There is also a need to consider the application of more frequent Mectizan treatments, possibly with adjunct measures, such as...
ground-based vector control in selected areas, or new chemotherapeutic approaches (as and when they become available).

Link: http://www.tandfonline.com/doi/abs/10.1179/136485908X337481


Abstract: The donation of ivermectin (Mectizan®, Merck & Co., Inc.) to control onchocerciasis (river blindness) was established in 1987 and has since gradually expanded to provide for >570 million treatments cumulatively over the past 20 years. The Mectizan Donation Program (MDP) operates within a broad partnership in 33 endemic countries in need of mass treatment. Particular operational methods and tools are applied to facilitate ivermectin mass treatment. Drug management has been streamlined, including dosing, tablet size and packaging, and monitoring for adverse events. Much of the experience gained in the development of ivermectin mass treatment can be usefully applied in the recent broader perspective of control of neglected tropical diseases. The most important operational lessons of the MDP include: (i) the need to easily define the target population for treatment using rapid, non-invasive techniques; (ii) the value of a broad partnership; (iii) the great potential of working through community-directed treatment; (iv) the need to streamline all drug management aspects and (v) the importance of operations research to tackle new challenges.


Abstract: This Note explores the economic and social factors that drive multinational pharmaceutical companies to donate drugs to developing countries and evaluates the effectiveness of such donations in combating medicine shortages. The Note poses that such donations provide necessary economic incentives to drug companies and help curb high medical prices in developed nations while being an essential tool for ameliorating intellectual property requirements imposed by TRIPS. The Note proposes two solutions to further incorporate donations in access to medicine relief efforts and advocates increased international cooperation in the practice.

Link: https://muse.jhu.edu/article/547379/summary


Abstract: The guidelines are intended to improve the quality of medicine donations in international development assistance and emergency aid. Good medicine donation practice is of interest to both donors and recipients. Guidelines for medicine donations is based on four core principles that form the basis of good medicine donation practice, namely: 1. Donations of
medicines should benefit the recipient to the maximum extent possible. All donations should be based on an expressed need. Unsolicited medicine donations are to be discouraged; 2. Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with the government policies and administrative arrangements of the recipient country; 3. There should be effective coordination and collaboration between the donor and the recipient, with all donations made according to a plan formulated by both parties; 4. There should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

Link: [http://apps.who.int/iris/bitstream/10665/44647/1/9789241501989_eng.pdf](http://apps.who.int/iris/bitstream/10665/44647/1/9789241501989_eng.pdf)

* For the purposes of this review, we have established three categories to describe the state of the literature: thin, considerable, and rich.
  - Thin: There are relatively few papers and/or there are not many recent papers and/or there are clear gaps
  - Considerable: There are several papers and/or there are a handful of recent papers and/or there are some clear gaps
  - Rich: There is a wealth of papers on the topic and/or papers continue to be published that address this issue area and/or there are less obvious gaps

Scope: While many of these issues can touch a variety of sectors, this review focuses on medicines. The term medicines is used to cover the category of health technologies, including drugs, biologics (including vaccines), and diagnostic devices.

Disclaimer: The research syntheses aim to provide a concise, comprehensive overview of the current state of research on a specific topic. They seek to cover the main studies in the academic and grey literature, but are not systematic reviews capturing all published studies on a topic. As with any research synthesis, they also reflect the judgments of the researchers. The length and detail vary by topic. Each synthesis will undergo open peer review, and be updated periodically based on feedback received on important missing studies and/or new research. Selected topics focus on national and international-level policies, while recognizing that other determinants of access operate at sub-national level. Work is ongoing on additional topics. We welcome suggestions on the current syntheses and/or on new topics to cover.