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Working Paper

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2014/19/TOM/ISIC
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ABSTRACT

The continuing economic downturn, which impacts health systems around the globe, will lead to more requests for medicine donations in the future. This discussion paper analyses the context in which cross-sector partners (pharmaceutical manufacturers, non-governmental organizations (NGOs), and local health institutions) can work together to give beneficiaries access to medicines donated by manufacturers in emergencies and non-emergencies. These cross-sector partners need to be aware of all stakeholders and ethical dilemmas that a medicine donation may pose. In an effort to address medicine donations under a holistic approach for the first time, we identify four factors that hinder supply chain performance: problematic assessment of demand, opaque supplies for donations, lack of funds for medicine distribution, and fuzzy communication among partners. We describe how partners in supply chains of medicine donations can tackle these issues by (a) setting up new or managing existing partnerships, (b) mapping current supply chains in emergencies and non-emergencies, and (c) managing a harmonized supply chain through transparent end-to-end flows. Once partners apply these design elements, they will make a step forward in ensuring that donations are needs-driven and based on an understanding of local cultures.

Keywords: Medicine Donations; Global Health Supply Chains; Cross-sector Partnerships
1. INTRODUCTION

“As to diseases, make a habit of two things: to help; or at least to do no harm”, Hippocrates said referring to the way doctors should practice medicine (Grammaticos et al., 2008). Used appropriately, medicines are a necessary tool to ease human suffering from preventable diseases\(^1\). In those parts of the world where people cannot afford buying medicines, donations often bridge the gap between the needs and the limited capacity of individuals and governments to purchase the medicines. For example in 2001, the United Republic of Tanzania closed their 30% gap in medicine procurement by donations (Mariacher et al., 2007). Last August, the World Health Organization (WHO) reported that 700,000 people were in dire need of medicines and medical supplies\(^2\) in Syria where the local pharmaceutical production decreased sharply (UN News Center, 2013).

Medicines are donated in a plethora of different ways, for example: pharmaceutical manufacturers donating branded medicines, contract manufacturers donating generics\(^3\), and consumers or international and local wholesalers offering medicines previously purchased by them. For-profit manufacturers usually donate branded medicines on a larger scale than generics manufacturers, wholesalers, and consumers do (Green, 2013; ATMI, 2012). We focus on flows of in-kind donations of medicines by manufacturers.

There are two different types of medicine donations. Emergency donations include medicines given during and after a natural or manmade disaster to satisfy the temporary needs of victims. Non-emergency donations include all medicines used to strengthen a national or local healthcare system with the ultimate goal to improve public health in developing countries. Examples of non-emergency donations are the disease-specific programmes with which manufacturers aim to prevent or cure the transmission of a neglected tropical disease in a targeted population (IFPMA, 2012). Also non-emergency donations targeting low-income patients are common in developed countries (Banco Farmaceutico, 2013). Although emergency donations are subject to more constraints due to the urgency, intensity, and uncertainty of the situation, problems in medicine donations supply chains are

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\(^1\) Preventable diseases are those for which a treatment has been found, which can be sold to patients.

\(^2\) Medical supplies include needles, syringes, bandages and dressings.

\(^3\) A generic is a medicine that is comparable to a branded medicine in dosage form, strength, route of administration, quality and performance characteristics, and intended use (FDA, 2013: 7).
rather similar in emergency and in non-emergency situations (Van Dijk, 2011). In this discussion, we include both emergency and non-emergency donations.

But how come pharmaceutical manufacturers have inventory available for donation? Manufacturers want to offer high service levels to their customers, which is why production tends to exceed predicted demand. When medicines cannot be sold, they remain in the warehouse until expiry and are then disposed of by therapeutic class. The dilemma lies in the fact that quality medicines become waste which could otherwise have helped many beneficiaries. Furthermore the environmental impact of the incineration of medicines is significant (WHO, 1999).

Although medicine donations can ease human suffering, they have frequently been criticized (Purvis, 1996). The common perception that any medication is better than nothing is rather misleading. Inappropriate donations include donations of outdated medicines, of medicines in excess quantities, of returned medicines from patients, and of free samples (WHO, 1996). These donations can be useless, dangerous and may create additional problems in the recipient country.

No matter whether in emergencies or non-emergencies, the problems caused by inappropriate donations can be tremendous for the recipient country. Expired or spoiled medicines need to be incinerated or buried in concrete with recipient countries usually not having the financial or technical means for proper destruction or disposal (Nemecek, 1998). Central governments of recipient countries might also cut the budget of Ministries of Health (MoHs) by the equivalent value of donated medicines. Since pharmaceutical companies tend to value their donations as high as possible (due to tax incentives), the negative financial impact of the donation on the budget of MoHs increases (Hogerzeil et al., 1997).

Medicine donations may have negative effects for local markets as well. Baker et Ombaka (2009) claim that medicine donations capture market share and suppress competition as manufacturers of generics are discouraged to invest in these countries. The above mentioned problems can be attributed to the dominantly supply-driven donation practices in which pharmaceutical companies donate excess medicines to groups of recipients, not necessarily based on expressed needs.

Yet these problems do not seem to slow down the pace at which medicine donations are made due to growing demand for medicines. The population growth in many of the least developed countries

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4 UDG, a UK-based medicines pre-wholesaler, destroyed several thousand medicines out of the total supply it received (N.Blurton, personal communication, June 15, 2013). Pre-wholesalers usually work in a vendor-managed setting and offer warehouse management, sales order handling, invoicing, cash collection, and consulting to wholesalers.
(LDCs) leads to an increase in the number of people in need of medicines. In middle-income countries (MICs) not everyone benefits from the growing per-capita income.\(^5\) The rising debt of some developed countries excludes poorer sections of their populations from basic health care provision. On top, more and more people are affected by natural or manmade disasters (IFRC, 2013). Patterns such as these will not only lead to growing demand for medicines, but also fuel the trend for more medicine donations (P. Gradnik, personal communication, September 2, 2013).\(^6\)

Matching demand with supply in supply chains of medicine donations is more complicated than it first appears. It assumes a sound knowledge of the needs, understanding of the local conditions, detailed data on the quality and quantity of the medicines available, and compliance with a complex set of international and national regulations for donations. It is obvious that these challenges can be overcome more easily in cross-sector partnerships among manufacturers, international and local non-governmental organizations (NGOs), local health care service providers, and governments. The collaboration of the for-profit and the non-profit sector is frequently mentioned as the most suitable response (Reich, 2000; Green, 2013).

This paper addresses the design of medicine donations supply chains in strong partnerships between the for-profit and non-profit sectors. Such partnerships can make a difference also with regard to complementary interventions, such as transfer of skills, health education, and advocacy, all of which are needed for the impact of medicine donations to be more efficient and sustainable. We stress the importance of mapping the existing medicine donations supply chains and of managing the end-to-end flows of cash, medicines, and information.

In the following section, we provide a comprehensive literature review to map the variety of medicine donations programmes and the existing gaps in academic research. Medicine donations supply chains involve four levels of partners who need to be aware of the stakeholders\(^7\) they affect with their operations and the ethical dilemmas they may face. A more detailed overview of the ecosystem of medicine donations is given in the third section. The fourth section discusses the factors we identified

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\(^5\) Medicine donations are currently limited to communicable diseases. However, the WHO found that non-communicable diseases (cardiovascular disease, diabetes, cancer, and chronic respiratory diseases, osteoporosis, Alzheimer's disease, etc.) affect nearly 80% of the populations in MICs and LDCs (WHO, 2013a). This further increases the burden of governments for financing public health.

\(^6\) Donations will continue to be made from the US and Europe, but new countries are likely to enter the scene. The economic transition of some MICs – notably Brazil, Russia, India, China, South Africa, Mexico, Indonesia, South Korea, and Turkey – and their increased political influence in the global system means that pharmaceutical manufacturers from these countries could emerge as new donors.

\(^7\) In an organization, a stakeholder is any group or individual who can affect or is affected by the achievement of the objectives and activities of this organization (Freeman, 1984: 52). Stakeholders differ from organization to organization, and they can change dynamically (Sillanpaa et al., 2005).
as hindering the matching of medicines demand with supply. In section five we propose a three-component approach to tackling the most common problems related to the management and operations of cross-sector partnerships for medicine donations. In the final section we summarise the contributions of our paper and make suggestions for future avenues of research.

2. LITERATURE REVIEW

Many different medicine donations programmes support people in need. As part of the Mectizan Donation Program (MDP), Merck donated nearly 1 million treatments of ivermectin to various countries since 1987 (Burnham et al., 2004). Two US NGOs made 16,566 shipments of donated medicines between 1994 and 1997 to a total of 129 countries (Reich et al., 1999). In the State of Gujarat (India) 1,308 tons of drugs were donated following the earthquake in 2001 (WHO, 2011).
One would expect donations programmes to run smoothly because manufacturers and NGOs have experience in supporting people with medicines. The real case proves to be more complex since in literature we found only two emergency situations with limited inappropriate donations: in East Timor and in the State of Gujarat, India (Autier, 2002). Scholars tried to explain why there were only few inappropriate donations in these two emergency situations and they concluded that the success of both cases was due to special characteristics of the region where the emergency occurred. By not addressing common patterns that exist in many emergency donations, the importance of efficient supply chain management has not been sufficiently recognized yet.

In non-emergencies, a few cases of medicine donations are considered successful because the quality of life of patients was improved. The majority of these cases took place in partnerships for disease-specific programmes (IFPMA, 2012). In all the other studies on non-emergencies, it seems inappropriate donations could be avoided if end-to-end supply chain monitoring existed. This would enhance effective communication between donors, intermediaries and beneficiaries, and also provide a good match of demand and supply and ensure high quality of donated medicines (Mariacher et al., 2007).

In view of the scale of emergency and non-emergency donations, the scarcity of academic literature on medicine donations is remarkable. The only review we found reports 25 studies published after 1999, including both academic and grey literature (technical reports, working papers). This dearth of publications may lead to the false conclusion that the number of medicine donations, and related problems, has decreased over the last years. The revision of the WHO guidelines in 2010 and our interviews with health experts imply that inappropriate donations continue to happen (P. Yadav, personal communication, January 8, 2013; Yin, 2012; WHO, 2011).

The vast majority of studies we identified (25 out of 33) are qualitative analyses, which may be due to the fact that governments and NGOs usually do not collect or keep data about their operations (Van Dijk et al., 2011). This may be justifiable in emergency situations, but not in non-emergencies where resources (time, funds, and personnel) can and should be allocated to data collection. In either case, the lack of data on medicine donations precludes a clear view on the supply chains that are in place. Consequently, we found no academic research on medicine donations supply chains.

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8 For East Timor, the few inappropriate donations were attributed to: a) the topography of the region (island) allowed goods to be transported only by air and sea, both of which facilitate tight controls, and b) the compliance of NGOs with the guidelines to donate the WHO recommended New Emergency Health Kit. For the State of Gujarat, the manufacturing and distribution of donated medicines took place within India. Thus no problems were observed with labelling, expiry dates, and distribution of donations.
The academic literature we found on medicine donations focuses on donations in emergencies (17 out of 20) and mainly consists of discussion papers about ethics, guidelines, and policies for medicine donations (Van Dijk et al., 2011). There is hardly any literature on donations in non-emergencies.

A lot of grey literature has been published by multilateral agencies (e.g. the WHO, the World Bank), governments (e.g. the US Food and Drug Administration (FDA)), and practitioners (e.g. Doctors Without Borders, Pharmacists Without Borders, etc.). The emergency situations they study (e.g. East Timor, El Salvador, Mozambique, State of Gujarat, Aceh, and Sri Lanka) have not been echoed in academic research. Some of these reports offer interesting findings, for instance, when US manufacturers donated medicines, the public sector was charged, due to tax deductions, four times more than the case in which the equivalent generics would have been bought, or if branded medicines had been sold at differential prices (Guilloux et al., 2000).

Most studies focus on the motives and contributions of one of the partners (Van Dijk et al., 2011), failing to address the potential of cross-sector partnerships for medicine donations, and failing to analyse the entire supply chain from end to end. Disease-specific programmes are an exception, where business models and operations of different partners are analysed (Oyediran et al., 2002; Coyne, 2002). Out of the nine disease-specific programmes the International Federation of Pharmaceutical Manufacturers & Associations outlines (IFPMA, 2012), only for MDP, there is documentation describing the structure of its supply chain (Burnham et al., 2004).

Our literature review reveals that academic research on medicine donations is fragmented and limited. Analytical studies and those focusing on non-emergencies and supply chain management are even fewer. Practitioners and scholars agree that needs-driven medicine donations are run in accordance with good donation practices, e.g. the disease-specific medicine donation programmes, whereas push-driven medicine donations seem to encompass the majority of bad donation practices.

The contribution of our work to academic knowledge comes from the integrated approach we maintain by including in our scope emergency and non-emergency situations, and disease-specific programmes. We believe that medicine donations, aiming to serve any of the above goals, could be more efficient and effective if supply chain partners were committed to cross-sector partnerships. In particular, we try to give a comprehensive overview of the strategic and operational issues that complicate medicine donations. We study medicine donations holistically because management of cross-sector partnerships and supply chains proves to be equally crucial as data collection; an insight that has not been offered by previous authors.
3. THE ECOSYSTEM OF MEDICINE DONATIONS

Medicine donations have inherently complex supply chains because of the large number of partners, involving donors, intermediaries, recipients, from non-governmental and governmental organizations. Supply chains of medicine donations have various structures because they are affected by the policies and capacities of each of the partners. In emergencies, partners work under pressure to satisfy urgent needs for medicines, sacrificing sometimes the accuracy of estimating the needs (Van Dijk et al., 2011). In non-emergencies, partners can plan in advance for the matching of needs with medicine donations.

Building on various cases described in literature, we outline in Figure 1 the external and internal environments of medicine donations. The external environment refers to all the institutions that are beyond the control of the partners in medicine donations but still influence the supply chains. In scanning the internal environment, the differences in sourcing and distributing the medicines in emergency and non-emergency situations will become obvious, as well as major ethical aspects of medicine donations.
3.1 INTERNAL ENVIRONMENT: ROLES, PARTNERS, AND TYPES OF DONATIONS

Figure 1 illustrates four levels of partners in the medicine donations supply chain: donors, intermediaries, recipients, and beneficiaries. Adapting the WHO definitions, we classify as (Asher et al., 2000):

- **Donors**: organizations giving medicines on a non-profit basis. Donor organizations can be corporates donating branded medicines, manufacturers donating generics, and international or local wholesalers. We limit this discussion to organizations donating branded medicines since there is no significant evidence of donations by wholesalers. Generics manufacturers have started to make medicine donations only recently (ATMI, 2012).

- **Intermediaries**: organizations requesting and receiving medicines from donor organizations and distributing them to other medical organizations treating patients directly. We call them intermediaries due to their brokering nature. We predominantly refer to European NGOs accepting donations of manufacturers (e.g. International Health Partners (IHP), Tulipe, Action Medeor, Banco Farmaceutico). In disease-specific programmes, intermediaries are the WHO or partnerships including representation from local governments (e.g. the African Program for Onchocerciasis Control), and the World Bank.

- **Recipients**: organizations in direct contact with patients such as local NGOs offering their medical aid on-site in emergencies and non-emergencies (e.g. Magen David Adom, Medical
Refresher Courses for Afghans), WHO country offices, MoHs, charities, and individual health facilities.

- **Beneficiaries**: patients as individual persons or as communities in case of endemic infections or epidemic diseases.

It is important to mention that this is a generic representation of the potential levels in medicine donations supply chains. In practice, more than one recipient is often involved before a donation reaches a beneficiary. For example, local NGOs may use one part of a donation for the needs of their own programmes and pass-through the rest to various other health facilities, charities, and local NGOs. This makes tracking and tracing problematic if one considers that NGOs do not have the necessary resources and knowledge to systematically follow their donations in a standardized way.

In emergencies, the disruption of formal administrative systems affects a country’s capacity to ensure proper management and function of public health supply chains. Thus intermediaries typically use any available means to store, transport, and dispense the donated medicines (Autier et al., 2002). International NGOs help to meet the needs through buffer stocks during the first few days of the acute emergency and to coordinate recipient NGOs (PQMD, 2011).

In non-emergencies, donated medicines could be transferred from donor to beneficiary in many different ways: including intermediaries or not, moving the medicines from the donor’s warehouse to that of the intermediary, or passing the ownership to the recipient without physically moving the medicines to the intermediary. There are three levels through which a donation can enter the health supply chain of the recipient country (P. Yadav, personal communication, January 8, 2013):

- **National**: donated medicines pass through the central health care warehouse of the recipient country. The recipient MoH distributes the medicines following the national health care regulations of the respective country.

- **Regional**: donated medicines pass through a district or regional warehouse of the recipient country. In this case, donors typically engage with local or international NGOs: faith-based organizations, non-profit organizations or health foundations. The donated medicines are distributed to patients through the respective MoH-approved distribution channels.

- **Local**: donated medicines are received directly by the warehouse of an individual health care facility. These medicines usually are not distributed through the national distribution system and quality controls, if any, are performed by the facility.
### 3.2 EXTERNAL ENVIRONMENT: (POTENTIAL) POWERFUL STAKEHOLDERS

Medicine donations need to adhere to a mixture of international and national regulations. Compliance with the WHO guidelines is critical, making the WHO a prominent stakeholder of any medicine donation. In 1996, the WHO published its first version of guidelines for medicine donations to provide guidance to donors and recipients (WHO, 1996). To clarify issues that arose and to further ensure appropriate donations in emergencies and in non-emergencies, the WHO revised its guidelines twice, publishing the last version in 2010. The WHO has also published the List of Essential Drugs (LED), the core list indicating “minimum medicine needs for a basic health-care system, listing the most efficacious, safe, and cost-effective medicines for priority conditions” (WHO, 2010: n.p.).

The WHO guidelines are meant to be adopted and implemented by donors, intermediaries, and recipients, but they are not an international regulatory document - which prompted a debate about the level of their enforcement (Sukkar, 2009). These guidelines suggest governments to issue their own policies for medicine donations⁹. Not all developing countries have donation policies in place yet (Autier et al., 2002). Using the LED as a guide, each MoH develops its own national essential medicines list addressing specific diseases and commonly used medicines at all their health care levels. Donated medicines that do not appear in the WHO LED or the national list may complicate the administrative burden for recipients in emergencies, which may raise questions about the necessity of the donations (Reich, 2000). Therefore, if not included in the partnership as a recipient, the MoH can be a potentially powerful stakeholder.

Other potential stakeholders of medicine donations are the media (who can influence the supply chains by advocating or opposing medicine donations) and local pharmaceutical manufacturers. Since donations may decrease market share of local manufacturers, non-emergency donations affect these stakeholders directly (Baker, 2009). There is also a case of market distortion in emergencies (PSF, 2005). Thus there should always be solid arguments by the partners explaining their rationale for making medicine donations.

### 3.3 DONATIONS ARE PRONE TO ETHICAL DILEMMAS

Donating medicines can raise ethical questions about the incentives of the donors who are for-profit manufacturers of medicines. The WHO stresses the importance of donor commitment since inappropriate donations are perceived to be driven by manufacturers who want to avoid the costs of

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⁹ Examples of governments which followed the suggestion were the US FDA among developed countries and the Mozambique government among developing countries.
warehousing and disposal of their unsold medicines and who do not seem to care about the needs on the ground (Crooks, 1998). Despite efforts by the WHO, there is no evidence that recipients have the power or knowledge to refuse an inappropriate donation. In this section, all the above issues are discussed to describe some ethical dimensions of medicine donations supply chains.

Medicine donations can be driven by altruism or self-interest of manufacturers (Dabade, 2004). On the one hand, donations can be driven by the awareness of manufacturers that their medicines meet needs of people who cannot afford paying for them (Russo, 2008). This motive is closely related to altruism, a very important moral value that can partially explain the US-style philanthropy, with all the well-known pharmaceutical manufacturers, e.g. Merck, Janssen, Pfizer, Eli Lilly, engaged in running patient assistance programmes for US citizens (RxAssist, 2012; Reich, 2000).

On the other hand, according to a different stream of ethics literature, the primary moral obligation of individuals is to pursue their own welfare (Badhwar et al., 2013). This theory helps explaining other drivers connected to direct and indirect profits for pharmaceutical manufacturers (Russo, 2008; Reich, 2000):

- Obtaining tax deduction, or tax credits, or avoiding disposal costs, adding to direct profits.
- Accessing future markets through establishing relationships with partners that already operate in these markets.
- Being a socially accountable organization with proud employees and a tradition of collaborating with logistics companies and NGOs also generates indirect benefits for manufacturers. This explains why Corporate Social Responsibility (CSR) policies of pharmaceutical manufacturers typically include donations. CSR seems particularly important for EU-based manufacturers (P. Yadav, personal communication, January 8, 2013).

The above list may not be complete (and therefore needs further research), but a mixture of the above drivers can describe the motivation of the majority of pharmaceutical manufacturers when they choose to become donors.

Another issue inherent in medicine donations is the uneven distribution of power in supply chains. Donors exercise power by deciding about the time, type, and size of donations whereas intermediaries

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10 In the US, there is full tax deduction for medicine donations giving incentives to US-based pharmaceutical manufacturers. In the EU, medicine donations from manufacturers still seem to be at a very early stage compared to those from the US. The complexity of different tax, regulatory, and legal issues in the different EU states may act as disincentives for a manufacturer willing to donate to an intermediary NGO based in another country.
often feel obliged to accept any offered donation to assure that donors will continue providing them with free-of-cost medicines. Likewise, intermediaries also exercise power and influence over recipients and beneficiaries who may be unaware of the WHO guidelines (Mariacher et al., 2007).

Plato argued that when individuals gain power without accountability, they may use it unjustly (Frede, 2013). The WHO guidelines address this by stressing that the acceptance or rejection of a medicine donation lies with recipients. The WHO calls upon donors to assure that medicines will be administered safely by intermediaries and recipients (WHO, 2011). However, the guidelines do not make clear the responsibilities of recipients and beneficiaries to provide feedback. A way to ensure the accountability of donors, intermediaries and recipients still needs to be defined.

Underlying this discussion are basic questions about social justice. Should governments of recipient countries accept medicine donations in non-emergencies while being aware that they potentially increase their dependency on donors? Should manufacturers let governments off the hook to adequately finance public health? What should be the role of stakeholders such as the WHO, the media, and local manufacturers in developing countries?

It is beyond the scope of this paper to provide answers to the above ethical dilemmas. Once there is a well-defined strategy of donors, intermediaries, and recipients for medicine donations, partners should “do no harm” with their operations. They are urged to examine their motivation and commitment in advance because they need to be aware of implications for the recipient country, when potentially harming local production or influencing therapeutic options for treatment (PSF, 2005; Baker et al., 2008). Only targeted and properly managed medicine donations have the potential for filling an existing gap in supplies for emergencies and non-emergencies.

4. WHAT HINDERS THE MATCHING OF DEMAND WITH SUPPLY?

A mismatch between demand for medicines and supplies can occur in terms of timing, quantities, and beneficiaries. In for-profit supply chains, a mismatch means lost revenue because of lost sales or resources. In supply chains of medicine donations, the results of a mismatch can be vital for beneficiaries: shortage of supplies means that people will suffer for longer, and excess of supplies can distort local markets or lead to stocks of perished and potentially dangerous medicines. The severe ramifications of this mismatch prompt a continuous debate about practices applied by donors, intermediaries, and recipients (Yin, 2012; Crooks, 1998). Researchers and the WHO reviewed this problem to offer insights and guidance for all partners (WHO, 2011; Berckmans et al., 1997).
A few examples will illustrate the major factors we identified as obstacles to matching: problematic assessment of demand, obscure supplies for medicine donations, lack of funds for medicines distribution, and fuzzy communication among partners in the supply chains of medicine donations.

4.1 PROBLEMATIC ASSESSMENT OF DEMAND

One of the problems particularly affecting medicine donations is that estimation of demand is challenging: Which medicines are needed and how many will be enough, where are the affected populations located, and by when do the medicines need to be delivered?

In emergencies, one needs to establish what the needs are after a specific natural or manmade disaster. However, needs assessment is often neglected due to the urgency of the situation and the scarcity of available resources (funds, time, personnel). A case in point is the donation of an antibiotic by Eli Lilly to Rwandan refugees during the civil war between Hutus and Tutsis (Crooks, 1998). The miscalculation of the needs by a United Nations agency left many medicines unused until their expiry. This caused multiple problems, in terms of public relations and negative publicity for donors and intermediaries. Another case was Aceh (Indonesia) where no medicines were requested after a tsunami destroyed big parts of the province. However, 4,000 tons of medicines were donated for a population of 2 million people providing enough supplies for up to 8 years for some of the medicines, and thus distorting the market for local manufacturers (Hechmann et al., 2007).

In non-emergencies, forecasting of needs necessitates a thorough understanding of the local conditions in a specific developing country. Many of these countries lack basic data about medicine consumption rates and disease prevalence in their population, and don’t have the means to collect such data. Recognizing the importance of knowing the flows and the systems, the WHO has focused on building sustainable data collection capacity in sub-Saharan countries through investments for training and monitoring systems and in mapping medicine supply chains (Yadav, 2011).

The problem in non-emergencies is of a different nature since some of the necessary data exists through the WHO. A database informed periodically by the WHO, the Global Health Observatory, presents up-to-date information for diseases and needs of each country (WHO, 2013b). These data refer mainly to the national level, whereas data for the regional or the local level need to be gathered by the respective MoH. To the best of our knowledge, there is no indicator in the WHO country profiles which tracks donations accepted nationally and the priorities a government sets for distribution when deciding to accept donations. There are countries in which up to 60% of the population depends on NGOs and charities (Yadav, 2011). This implies that medicine donations are
common practice, but there are no available data to assess, for instance, which diseases or health care levels are mainly addressed by these donations.

4.2 AMBIGUOUS MATCHING FOR THE MEDICINES TO-BE-DONATED

Even if the problems for determining demand in emergency and non-emergency situations were resolved, it would still be difficult to assess available supplies of medicines for donations. In Europe, pharmaceutical manufacturers make medicine donations on an ad-hoc basis as a response to requests from intermediaries (A. Dunnett, personal communication, February 15, 2013). It is reasonable to assume that headquarters of manufacturers will not have a full overview on the flows of medicines from their warehouses in different countries, such as amounts of donated medicines, therapeutic classes, recipients and beneficiaries, and time until expiration. Without streamlined donation policies, the process of making a donation can be time-consuming for the staff, there is no guarantee for the manufacturer that the medicines will be distributed before their expiration dates, and that they will not end up fuelling parallel markets (AFP, 2006). Implementing standard operating procedures for donations could help manufacturers achieve transparency and avoid accusations by practitioners of donations of unsold stock.

Exceptions to the above are disease-specific programmes, e.g. the MDP or the Children Without Worms, that are a core part of CSR strategies and are run directly by the headquarters of pharmaceutical manufacturers. The long-term results manufacturers aspire to have, necessitates planning of the production of the donated medicines. Collaboration with the WHO for needs assessment and recipient feedback are other factors contributing to the success of these programmes.

Nevertheless, matching of demand with supply does not always happen at donor level. If a donation is not earmarked, intermediaries will decide what medicines will go to recipients to cover needs in emergencies or non-emergencies. To the best of our knowledge, no problems for matching of the needs were reported when the WHO acted as intermediary. But it is expected that intermediary NGOs will sometimes struggle to manage their supply chains in view of lack of permanent, skilled workforce, standard procedures, and stable financial resources.

What is more, operating models of intermediary NGOs are significantly diverse in different European countries:

a) IHP, in the UK, acts both in emergencies and non-emergencies. In non-emergencies, IHP a) runs programmes with MoHs, WHO country offices, and international NGOs, donating
medicines and providing skills nationally and regionally and b) creates partnerships with local NGOs donating medicines locally for use in specific health care facilities.

b) The French NGO, Tulipe, makes donations only to recipient NGOs operating during emergencies. The majority of these donations are directed to French-speaking African countries. Tulipe only engages in the preparation and provision of pre-packaged kits to its network of recipient NGOs.

c) Action Medeor, a German NGO, emphasizes the values of social justice and global solidarity in its vision statement (Action Medeor, 2012). For non-emergency situations, Action Medeor founded a subsidiary in Tanzania with production facilities and distribution channels, as well as training facilities.

d) In Italy, Banco Farmaceutico aims to address health poverty within the Italian market by connecting retailers – pharmacies – with local charities. During the past three years Banco Farmaceutico opened local offices in Spain and Portugal, focusing always on in-country problems.

With the exception of Banco Farmaceutico, these intermediary NGOs handle international donations. The amounts of medicines passing through the NGOs are significant. For example, IHP donated 3 million doses of Vitamin A as part of a non-emergency donation in Pakistan and, in 2011, Tulipe donated 20 kits (nearly one ton of medicines) to the Ivory Coast (IHP, 2012; Tulipe, 2013).

If donors choose intermediaries carefully, they can meet various needs of beneficiaries, because of the variety of emergencies and non-emergencies on which intermediaries work. However, this selection process of intermediaries would require the existence of documentation on supply chains and processes of intermediary NGOs. Currently, lack of such documentation prohibits an in-depth understanding of how things function at the operational level.

4.3 LACK OF FUNDS FOR MEDICINES DISTRIBUTION

For donors and intermediaries who want their donations to have a positive impact on recipient lives, distribution of medicines is a necessary and important part of the supply chain. The WHO guidelines suggest that donors have the responsibility for distribution of donated medicines. However, most of the times, donors handle the transfer of medicines until intermediaries receive the donation. This interpretation of the guidelines is convenient for donors, but it leaves the responsibility with intermediaries and recipients to find funds for distribution to beneficiaries.

Intermediaries often do not have enough funds for the distribution of medicines to recipients, which constrains their operations. For instance, Tulipe does not handle transportation of medicines to
recipient NGOs, while IHP relies on an agreement with DHL to use free space in DHL’s transportation means (A. Dunnett, personal communication, February 15, 2013).

Budgets of recipients are even more limited than those of intermediaries, which further narrows down the capacity of delivering medicines to the right beneficiaries (Yadav, 2011). In high-profile emergencies, recipients receive cash donations for distribution of medicines due to increased public attention. In non-emergencies, distribution of medicines runs smoothly only within disease-specific programmes.

4.4 COMMUNICATION AMONG PARTNERS

The lack of regular and harmonized communication among donors, intermediaries, recipients, and beneficiaries can lead to a roadblock for matching demand with supply. Pharmaceutical manufacturers rely on the ability of intermediaries and recipients to audit and report to them the impact of donations on beneficiaries.

In 2013, Johnson & Johnson and GlaxoSmithKline started giving deworming medicines (600 million doses) directly to the WHO. The beneficiaries for these donations are selected by national country programmes, reviewed by an expert panel of the WHO. The manufacturers are not involved in the selection process of beneficiaries and distribution channels, but require and receive feedback from the panel for the number of beneficiaries and current levels of disease prevalence. This is a typical structure for information flows for the disease-specific programmes in which the WHO is the intermediary.

Communication in global supply chains of medicine donations is always a tough goal to be accomplished (Coyne, 2002). Even in disease-specific programmes, beneficiaries found information flows to be problematic (Peters et al., 2004). However, it is important to be transparent through end-to-end information flows since the literature points to a link between the lack of supply chain transparency and bad donation practices in emergencies (Autier et al., 2002; PSF, 2005; Berckmans et al., 1996-1997).

Sharing information about a medicine donation is particularly challenging because there are no standard ways of reporting the size or the value of donations. In the past, manufacturers reported only the monetary value of their medicines and NGOs reported the monetary value of their shipments (PQMD, 2011). However, monetary value cannot easily be linked to the impact of donated medicines on the quality of life for beneficiaries. Therefore, an increasing number of manufacturers and NGOs
start report on the quantities of donations. Summarizing past and current practices, the main challenges are:

- Multiple units for measuring the size of medicine donations for which donors, intermediaries, and recipients may use: a) amounts of medicines (PQMD, 2011), b) packets (Xiao et al., 2010), and c) treatments11 (IHP, 2013).
- Multiple evaluation methods for establishing the value of medicine donations for which donors, intermediaries, and recipients may use: a) manufacturing cost, b) wholesaler cost, c) corresponding generic costs, and d) retailer cost (Autier, 2002).

Whichever practice partners follow, the result is that they cannot easily share information about their common operations since one unit or method cannot easily be converted to the other.

5. DESIGN ELEMENTS OF A HOLISTIC APPROACH

Despite the many challenges they face, cross-sector partnerships are considered by many experts as the only means to accomplish long-term results in public health (Colatrella, 2008; Reich, 2000). Building a cross-sector partnership is a highly relevant starting point for organizing medicine donations supply chains. Such a partnership aims at leveraging the complementary skills of different sectors and to provide solutions for public health problems that each sector struggles to address individually. However, the different organizations need time to develop a mutual understanding of their incentives, establish a common goal, and define clear processes accepted by each partner. Building these partnerships is a hard and resource-intensive task (Van Wassenhove, 2006; Reich, 2000; Peters et al., 2004), and it is important that all partners benefit from the outcomes (Colatrella, 2008).

The four factors discussed in the previous section that hinder the matching of demand with supply show that even cross-sector partnerships need to have specific characteristics for making successful medicine donations: a) partners need to learn how to interact among themselves and with some of their other stakeholders, b) partners are advised to map their internal operations, and c) partners should manage the supply chains of their shared operations through designing transparent and end-to-end flows of cash, medicines, and information (Figure 2).

11 A treatment is the average number of medicines needed to cure or prevent the disease of an individual (IFPMA, 2012).
Figure 2: A proposed holistic approach for medicine donations
5.1 INVESTING IN CROSS-SECTOR PARTNERSHIPS AND INCLUSION OF STAKEHOLDERS

In an ideal world, medicine donations would have no place because they create dependency of the beneficiary on donor goodwill. In reality, medicine donations serve both programmes intended to strengthen health care systems in non-emergencies and programmes to support victims of natural or manmade disasters.

In either case, the first step for partners is to agree on pursuing a shared vision. This will help partners narrow their scope on what to do by answering the following questions: What is the problem we are aiming to solve? Who are the beneficiaries? Are there different groups of beneficiaries? How do we create value for each group in three, five, or ten years? A needs analysis phase may prove advantageous at this stage of articulating the vision of a partnership.

Once the vision is defined, the next step is to define how the partnership will make its vision real. Partners need to agree on issues such as: Which are the resources that our vision requires? Do we need to coordinate only medicine donations or also complementary services? Who should be our key partners? Who are the other stakeholders? Which relationships should we establish with our partners and beneficiaries?

Succinctly written vision and mission statements, both on the individual and the partnership level, will facilitate the buy-in at all levels in the partner organizations. The top-management levels are the first allies to make a partnership work since without their consensus organizations cannot get involved in a cross-sector partnership, whether or not governed by a formal agreement. However, top-level managers need to ensure that middle and low-level managers share ownership of the projects in which the partnership will engage (Gatignon et al., 2009). The key is that these lower-level managers need to execute all policies and plans made by higher management levels.

Another critical step for a partnership is communicating its vision and mission to other stakeholders such as the WHO, local pharmaceutical manufacturers, and MoHs. Depending on the focus of their operations (emergencies, non-emergencies, or both) attention of partners can be directed to different stakeholders. Identification, prioritization, alignment, and integration of stakeholders can be easier in a partnership with a clear vision and mission, especially in non-emergencies. Addressing stakeholders and their concerns are challenging tasks, but there are many potential benefits that partnerships may enjoy: to foresee threats and opportunities, to minimize public criticism for operations, and to gain knowledge and expertise that each partner-organization may use individually in the future (Smith et al., 2008).
5.2 MAPPING INTERNAL OPERATIONS OF PARTNERS

Each partner in medicine donations supply chains has their own processes and systems. There is a need for each of these partners to help manage the supply chain as a whole, instead of sub-optimizing their parts. To do so, partners first need to understand their internal supply chains.

Our research shows that there is little documentation and quantitative data, especially in Europe, about medicine donations from pharmaceutical manufacturers and about operating models of intermediary NGOs. Future research can aim to cover the lack of documentation on supply chains and processes of intermediary NGOs. If partners would chart their own supply chains before starting the collaboration, it would significantly help assess the pool of available resources, the scale of current and the potential of future operations. If internal supply chain data are not available from manufacturers, we strongly propose the initialization of data collection, from each of their warehouses or centrally at headquarters of the manufacturers, so that they support cross-sector cooperation. The same applies to those intermediary NGOs which do not yet track medicine donations. If supply chain data do exist, but are considered to be sensitive, partners can select to be engaged in confidential studies separately from each other and to share only generic conclusions among themselves.

The process of knowing better the internal operations of each partner will significantly assist in understanding what they can contribute to and what they can gain from the partnership. Additionally, data are necessary to make an estimation of the size of supplies and the number of beneficiaries served by medicine donations. These estimations could be compared to the outreach of other models of improving access to medicines, for instance, equitable financing and affordable prices.

5.3 MANAGING AND DESIGNING END-TO-END FLOWS IN THE SUPPLY CHAIN

Despite the lack of data, the design of a single platform among partners might be the right approach to meet the needs of beneficiaries with medicine donations. After mapping and understanding their operations, partners will need to decide upon decision-making processes for their shared operations. This improves accountability of each partner, establishes rules for prioritization of needs, and helps assessing new initiatives given constraints of current resources. Thus decision-making processes have to address the full spectrum of partner planning.

As shown in the previous section, medicine donations supply chains are broken. Cash, medicines, and information flows receive little attention from partners, if they receive any attention at all.
Since the absence of cash can stop operations within a partnership, these funds are as important in medicine donations supply chains as in for-profit supply chains. Without sustainable solutions for providing cash for distribution, medicines will not reach beneficiaries on time. To provide a solution for the costs of handling and transporting the medicines, funds could be launched, similar to IHP’s Disaster Response Fund.12

Increasing the visibility of medicines moving along supply chains is crucial for evaluating the contribution of each partner. There are no standardized or optimized flows for donated medicines. Knowledge of medicine flows from donors to intermediaries, to recipients, and eventually to beneficiaries contributes to identifying the weakest links in these supply chains, which can prove helpful for building strong supply chains for medicine donations in emergencies.

A rare example of an intermediary NGO which ensures an end-to-end transfer of information in their supply chains is Banco Farmaceutico which created an online platform allowing donors and recipients to enter data and check the status of a donation (Banco Farmaceutico, 2013). Recipients declare their needs through the platform on a regular basis, while manufacturers get informed about actual beneficiaries. This virtual marketplace facilitates meeting supply with demand via a transparent and relatively simple process. Likewise, Tulipe chooses to visit, train, and audit at least three of their recipient NGOs per year. Tulipe then reports back to the French Pharmaceutical Companies Association (Les Entreprises du Médicament) the number of donations and the recipients (Tulipe, 2012).

Moreover, partnerships need to establish specific criteria for choosing intermediaries. This allows adequate auditing of these partners and their networks of recipients, which may result in long-term relationships based on good practices and trust.

To address the transparency of information flows, we suggest that partners pursue the standardization of measurement and evaluation methods in all their operations. Although it is unrealistic to assume that a manufacturer or an NGO would change their methods for reporting the size and impact of their donations, a tangible goal is the design of a conversion system that will allow one method to be comparable with the other.

Simplified and transparent reporting within such a partnership will allow pharmaceutical manufacturers to partner with those intermediary NGOs and recipient organizations which offer good

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12 Set up in 2012, the fund was used to ship medicines during the monsoons in Punjab (Pakistan) and the conflicts in the Pakistani Tribal Areas (IHP, 2013).
practices. This, in turn, will show the donors’ commitment to help and do no harm. It will also facilitate developing a sound business case for the entire pharmaceutical industry; for NGOs to request funding and prove their contribution to meeting needs; for governments to track donations and participate in discussions about international funding; and for policy makers to compare donations with alternative ways of building sustainable structures in health care systems.

In a partnership the focus needs to be on measuring if and how much donations improve beneficiaries’ lives. This can enhance sustainability of the partnership because meaningful metrics will help creation of a feedback loop between donors and beneficiaries. The challenge is to focus on metrics that link financial benefits for partners to impact for beneficiaries, to interpret them in a meaningful way, and to guide every partner to achieve a target.

It would be desirable to have quantitative studies on supply chains for medicine donations in the future, which use real-time data collected during emergency and non-emergency donations. Such studies could help model and optimize the medicine donations supply chains especially during non-emergency situations.

6. A PROMISING PATH

The majority of medicine donations lack a holistic approach towards partnerships and their supply chains. In this paper, we maintain an integrated, holistic view on cross-sector partnerships for medicine donations. First, we described the environment in which these partnerships are operating. Second, we analysed the factors we identified as decisive for matching of demand with supply. Third, we proposed specific steps for each of the three focus areas of our approach: investing in partnerships and inclusion of stakeholders, mapping the existing operations, and managing end-to-end flows in medicine donations supply chains.

We believe that manufacturers, intermediaries, and recipients are likely to contribute and benefit more if they are involved in cross-sector partnerships. Understanding the needs of beneficiaries, calculating the available supplies of manufacturers, ensuring the availability of financial resources, and fostering a continuous two-way communication are potential starting points for a future agenda for such partnerships. After having addressed these issues, partners have the opportunity to ensure successful design and smooth implementation of their operations. To create value for beneficiaries, partners need to aim at establishing a well-designed, needs-driven, pooling mechanism for medicine donations that will ensure putting the right medicine, in the right amount, at the right place, in the right time, and for the right beneficiary.
Based on our analysis, we suggest that in terms of research more attention needs to be paid to common patterns in emergencies and more focus needs to be put on non-emergencies and the supply chains that are in place. A useful source for collecting empirical knowledge could be case studies and survey methodologies for corporates and NGOs. The insights of those studies could serve to feed analytical models that would optimize the performance of medicine donations supply chains. Finally, while optimizing medicine donation supply chains is important for ensuring that beneficiaries receive the medication they need, we suggest that more studies could concentrate on CSR strategies for improved access to medicines, in order to help cross-sector partners work together.


