Good governance for medicines initiatives:
Exploring lessons learned

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Contents

Abstract

Corruption in the pharmaceutical system results in wasted resources, limited access to health services and reduced health gains. In this U4 Issue paper, we examine select global initiatives in the area of good governance and medicines that have been applied since the year 2000. These initiatives taken by the World Bank, the WHO and the Global Fund, as well as the Medicines Transparency Alliance, have been particularly useful in generating a political and policy dialogue around the issue of pharmaceutical system good governance. The main findings include that these initiatives identify weaknesses in the pharmaceutical system and can provide important baseline data. They have had the most value in generating a greater awareness about the issue, and in some instances they have also created important multi-stakeholder alliances and implemented sector-specific governance initiatives. However, there is often a significant gap between the identification of problems, the strategic design to address problems and their implementation. The tools used are often focused on the rules, procedures and practices that are assumed to prevent corrupt practices in the public sector, but they may not capture sufficiently well the complex dynamics that lead to corruption. Recommendations include the need for political analysis, and monitoring and evaluation – particularly with regard to the measurement of results – and the streamlining and uniformity of assessment tools across institutions.

Acknowledgements

About the authors

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1. Introduction

The pharmaceutical system's vulnerabilities to corruption are increasingly understood as a pervasive problem with negative effects on health status and social welfare (Vian, 2008). Corruption in pharmaceutical systems compromises governments' abilities to provide safe and reliable access to medicines for their populations and their capacity to provide the highest attainable standard of health. It is well known that the global pharmaceutical market is enormously lucrative, with annual global pharmaceutical spending being forecast to reach USD1.2 trillion by 2016, and annual spending growth will increase from USD30 billion in 2012 to USD70 billion in 2016 (IMS Institute for Health Information, 2012). Pharmaceutical expenditures can reach as high as 50% of the total health spending in some developing countries, and are typically one of the top health-care expenditures for governments globally (World Health Organization, 2012b). The World Health Organization (WHO) estimates that by improving access to existing essential medicines and vaccines, approximately 10 million lives per year can be saved (World Health Organization, 2004). If corruption occurs in the pharmaceutical system, it results in significant financial losses, and creates a serious threat to public health, patient safety and human rights.

Global organizations and donor-funded organizations such as the World Bank, the WHO, the Medicines Transparency Alliance (MeTA) and the Global Fund for AIDS, Malaria and Tuberculosis (Global Fund) are attempting to address corruption in the pharmaceutical system through improving its governance. In this U4 Issue paper, we undertake an examination of some of the global initiatives in the area of good governance and medicines that have been developed, piloted and initiated since the year 2000. Good governance is understood here to cover management practices that are participatory, consensus-oriented, accountable, transparent, responsive, effective and efficient, equitable and inclusive, and that follow the rule of law.1 These initiatives are also important insofar as good governance ideally reduces the likelihood of corruption.

To the best of our knowledge, this is the first study to examine the strengths and weaknesses of leading global initiatives in the area of pharmaceutical good governance. As such, there are limits to the study insofar as there is very little documented "hard" evidence on the results of these initiatives, particularly in terms of how they may improve a population's access to essential medicines. Also, given the diversity of the activities of the organizations and the variability of available baseline or external assessments, comparisons are difficult to draw. This paper is therefore, an initial effort to explore these issues with the hope that it will lead in time to deeper efforts to identify the cause and effect of pharmaceutical good governance interventions.

The purpose of this paper is to explore lessons learned based on established global initiatives in the area of pharmaceutical good governance, and is aimed at addressing the challenges in the pharmaceutical system. Our primary objective is to describe the approaches of the select institutions, and highlight the strengths and weaknesses of each and identify the results where possible. Lastly, we draw some core lessons wherever possible in order to inform donors and policy makers as they continue to implement pharmaceutical good governance.

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1 Economic and Social Commission for Asia and the Pacific. *What is good governance?* http://www.unescap.org/pdd/prs/ProjectActivities/Ongoing/gg/governance.asp (Accessed January 11, 2013)

2. Methodology

This research primarily focused on official documents from the four initiatives reviewed, and searches of the primary websites were performed to retrieve annual reports, country progress reports and other available documentation. For the Global Fund, this included audits by external organizations that had been publicly released by those organizations. Research on the World Bank also included project database searches using the following terms in various combinations – "pharmaceuticals", "corruption", and "governance". Finally, searches through Google Scholar, Google, Factiva and Summon (University of Toronto article database search) were performed to obtain press articles from key events and reviews of the organizations. Twenty-two semi-structured interviews with representatives from the World Bank (3), the WHO/GGM (5), MeTA (14) and the Global Fund (1) were conducted, along with interviews with the independent consultants (1) who participated in the implementation of the pharmaceutical good governance initiatives (some informants were involved in more than one initiative). In the interest of respecting key informants, findings from the interviews were not attributed to individuals, but were grouped and generalized where possible. The findings and conclusions in this paper are also informed by the combined experience of both the author J. Kohler and peer reviewers, all of whom have extensive experience working in the area of global pharmaceutical good governance. This paper also includes some country case studies in the Annex (Jordan, Philippines and Zambia) to help provide some specific details on how good governance initiatives are having an impact in different countries.

3. The pharmaceutical system

The pharmaceutical system is a complex area, encompassing the actions of public and private stakeholders as they move drugs through the supply chain from purchasing to providing to patients. The system is typically challenging to govern, as it is characterized by multiple failures. For example, there are information gaps at all levels, including between the consumer and the health-care provider (in terms of prescription drug choice), the health-care provider and the manufacturer (in terms of the therapeutic qualities of the product) and even between the manufacturer and the government. The market is also distorted by patent protection, which allows companies to hold monopolies on product sales. This prevents price competition until the patents expire, at which point generics can compete, ideally leading to lower prices.

There are several core decision points in the supply system, ranging from manufacturing to service delivery, each of which must be recognized and understood so that corruption cannot thrive out of ignorance (Cohen, Cercone, & Macaya, 2002). By understanding the multiple decision points along the value chain of the pharmaceutical system, decision makers can determine where and how corruption can occur and implement anticorruption strategies to improve transparency and accountability. Each core decision point needs to function well so that the system as a whole can offer safe, efficacious and cost-effective quality medicines. Even having one decision point vulnerable to corruption puts the integrity of the entire system at risk, potentially compromising the population's access to essential medicines. Nonetheless, the impact on health outcomes may also vary depending on the institutional organization of the system, the depth of the corruption problems and dynamics and possibly the level of "state capture" (See Table 1).

Manufacturing process

Table 1 shows there are established standards throughout the manufacturing process, and if these are not in place, there are risks to the quality of the medicines produced, as well as the risks of the occurrence of counterfeit, fake or substandard medicines increase. Furthermore, manufacturers, public regulators and drug inspectors are all responsible for ensuring good practices in the manufacturing process.

Registration

Drug regulatory agencies are also often responsible for the setting and enforcement of standards, licensing, defining the requirements for the marketing and the usage of medicines. Examples of potential vulnerabilities in registration include: i) the legal basis for the drug registration may be weak, vulnerable or flawed; ii) suppliers may pay government officials to register their medicine without the requisite information; iii) government officials may deliberately delay the registration of a pharmaceutical product to favour market conditions for another supplier; or iv) officials may deliberately slow down registration procedures to solicit payment from a supplier. In short, governments need to create drug registration systems to ensure that uniform standards are applied. However, and somewhat paradoxically, public intervention in the registration process also creates opportunities for corruption if there is a lack of good governance in the system.

Table 1: Key pharmaceutical system decision points and related processes that may be vulnerable to corruption

Decision point	Processes
Manufacturing	• Adherence to Good Manufacturing Practices (GMPs) • Quality management • Packaging and labeling • Active Pharmaceutical Ingredients • Master, batch and laboratory control records • Production and in-process control • Certificates of analysis • Validation • Track complaints and recalls
Registration	• Full registration or abbreviated drug applications • Safety and efficacy • Labeling • Marketing • Indications • Pharmacovigilance and warnings • Batch testing • Reevaluation of older medicines
Selection	• Determine budget • Assess morbidity profile • Determine medicine needs to fit epidemiological profile • Cost/benefit analysis of medicines • Consistency with WHO Model List of Essential Medicines (and other evidence-based) criteria • Pricing and reimbursement decisions
Procurement	• Determine model of supply/distribution • Reconcile needs and resources • Develop criteria for tender • Issue tender • Evaluate bids • Award supplier • Determine contract terms • Monitor order • Make payment • Quality assurance
Distribution	• Import approvals • Receive and check medicines with order • Ensure appropriate transportation and delivery to health facilities • Appropriate storage • Good distribution practices and inventory control of drugs • Demand monitoring
Prescription and dispensing	• Consultation with health professional • Inpatient and outpatient care • Dispensing of pharmaceuticals • Adverse drug reaction monitoring • Patient compliance with prescription

Manufacturing section adapted from Food and Drug Administration 2000 (Cohen, Mrazek, & Hawkins, 2007).

Selection process

The selection process is another critical point in the chain, and different countries use the selection process in different ways. Drug selection can involve decisions about which drugs can be imported or sold, which drugs the public sector will purchase and sometimes the patient eligibility for reimbursement. A common tool that many developing countries use in the selection process is an essential medicine list based on the World Health Organization Model List of Essential Medicines. This list has helped increase objectivity and transparency in the selection process by listing cost-effective medicines according to their international non-proprietary (generic) names, thereby further stimulating generic competition (Vian, 2005). Essential medicine lists may be implemented at the state/provincial or national levels of government. However, the essential medicine list is only one part of the process and depends on a selection process that needs to be institutionally sound, as manufacturers have a strong interest in getting their products listed. Therefore, when institutions are weak and individuals have incentives to engage in corrupt activities, the selection process can be tainted with payoffs, which can cause the national medicine list to include medicines that are neither appropriate nor cost-effective.

Procurement of publicly funded medicine supplies

The procurement of publicly funded medicine supplies is particularly susceptible to corruption because medicine volumes are usually large and the value of contracts is high, thus making it a very lucrative opportunity for suppliers. Domestic or international suppliers may pay public officials bribes to gain an advantage at any of several steps in the tender process, and biased procurement methods can also be employed, such as the use of direct purchases when there is no emergency to justify them.

Storage and distribution system

Opportunities for the diversion and theft of goods are present in all stages of the storage and distribution system, e.g. airport or sea workers can possibly plunder shipments and crime syndicates may steal large quantities from customs warehouses, airport fields and elsewhere. Additionally, medicines may be sold by drivers at markets along the delivery route during transportation, large quantities may be diverted to the black market and politicians and local leaders may divert supplies to their supporters or patronage networks, while health facility staff may resell subsidized medicines or steal medicines for use in their own private practices (Cohen, Mrazek, & Hawkins, 2007).

4. Select pharmaceutical good governance initiatives

The paper focuses on three global institutions: the World Bank, the WHO and the Global Fund, and one donor-funded initiative - the Medicines Transparency Alliance (MeTA). The institutions and donor initiatives were selected because they have all initiated specific pharmaceutical good governance initiatives. The World Bank is both a direct "hands-on" and a "hands-off" funder of global governance initiatives, and had the earliest initiatives in this area and is therefore discussed first. By contrast, the WHO offers technical assistance, primarily doing this through its Good Governance for Medicines Programme (GGM), which was launched in 2004. MeTA was piloted by the United Kingdom Department for International Development (DFID) in collaboration with seven pilot countries, the World Bank and the WHO, and its primary role and contribution has been to build up multi-stakeholder alliances in the area of pharmaceutical data disclosure. Lastly, the Global Fund is discussed, which has a different role than the others, insofar as it is a "hands-off" funder that incorporates good governance monitoring in its country grants.

4.1   The World Bank and good governance in the pharmaceutical system

In 1996, then World Bank President, James Wolfensohn, publicly acknowledged the risk of corruption for development outcomes, hence marking a major shift for the World Bank, as corruption was not openly addressed prior to this, which helped to initiate its operational and policy work on corruption and development. The current overarching guideline for the World Bank's efforts on corruption is its official Governance and Anticorruption Strategy, which was approved in 2007. Following a large Governance and Anticorruption Strategy Evaluation Report released in 2011 (World Bank, 2012), a revised strategy was recently updated in March 2012. The Governance and Anticorruption strategy notes, "…the sector level provides a potentially important entry point for governance reform", a commitment maintained in the revised strategy (World Bank, 2007; World Bank, 2012). Within the World Bank, the Poverty Reduction and Economic Management Network (PREM) is charged with leading governance work.

The World Bank has acted upon issues in pharmaceuticals and corruption from several directions, thereby ensuring good practices within their own projects, including strategies for pharmaceuticals in broader health systems projects and in projects targeting the pharmaceutical system only. The World Bank's interest in the issue was first highlighted in a 2000 Discussion Paper (Govindaraj et al., 2000),[2] with its first comprehensive pharmaceutical good governance analysis conducted in Costa Rica, which included a study that evaluated the vulnerability of the pharmaceutical system to corruption (Cohen et al., 2002). Five decision points were targeted: registration, selection, procurement, distribution, service delivery and use (Cohen et al., 2002), and the study used both qualitative and quantitative indicators to determine vulnerability. The study found the greatest weakness in Costa Rica to be in the procurement stage, where there was no tracking of purchases and/or suppliers, a lack of clear "standard operating procedures" and weak penalties for poor performance (Cohen et al., 2002). The second most vulnerable area was the distribution process, where there was a lack of monitoring of inventory and product movement (Cohen et al., 2002). This methodology was later used as the basis for the WHO's transparency assessment instrument as part of the Good Governance for Medicines Programme (Baghdadi-Sabeti, Cohen-Kohler, & Wondemagegnehu, 2009), and since this initial work,

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[2] Prior to this, specific studies on the issue of corruption and the pharmaceutical supply chain were also undertaken in Brazil (Cohen et al., 2000) and Chile (Cohen and Montoya, 2001) although the Costa Rican study was the first to establish measurements for good governance. The Brazilian study identified numerous weaknesses throughout the supply chain, which included a lack of enforcement of regulations, insufficient and inappropriate supplies of medicines and weak procurement capacity (Cohen et al., 2000). The Chilean study focused on the procurement process and highlighted the benefits of an electronic bidding process, which promoted transparency in the purchasing process (Cohen & Montoya, 2001).

programmes have targeted the effective operation of pharmaceutical systems, though there has been minimal comprehensive governance, transparency and corruption-specific programming for the pharmaceutical system.

One of the cornerstones to the World Bank's efforts in pharmaceutical governance is strong procurement guidelines for pharmaceutical products. While relevant for pharmaceuticals, the procurement guidelines are applicable to all contracts for goods, works and non-consulting services financed in whole or in part from World Bank loans. These guidelines may help curb corruption to ensure a good quality of procured medicines. These are monitored through audits and the World Bank has had to deal with the issue of corruption in its health projects, which has led to an effort to revise its current guidelines. In 2007 in particular, there was a high-profile case of corruption in pharmaceutical procurement in health projects in India. The World Bank's Detailed Implementation Review of India conducted in Fiscal Year 2007-2008 included a broad-based forensic review of procurement practices in five health projects involving procurement. The review found indicators of fraud and corruption in all projects, which affected outputs (World Bank Group, 2008), with the corruption practices including collusive behaviour, bribery and manipulated bid prices, broken or damaged equipment certified as compliant with specifications, the under-delivery of services, inadequate project audit and control systems. Nestor Pharmaceuticals Limited and Pure Pharma Limited were found guilty of collusive behaviour under the Reproductive and Child Health Project in India, and were barred from participating in World Bank procurement tenders for a set period of time as punishment. Moreover, the programme was suspended given these findings. In 2008, specific initiatives were begun to improve governance in the overall pharmaceutical system in India through the existing health project, such as the publication of all procurement processes, bidding, tightening of Non-Governmental Organization and contract awards, in addition to the expediting of complaint processing, improvements in quality control and procurement audits.

The pharmaceutical system has also been addressed through health-care systems-oriented projects that adopt different approaches depending on the country context. For example, in low-income countries the World Bank focuses heavily on the supply chain and on ensuring that medicines are reaching the patient. For middle-income countries with health insurance and drug benefits, the focus has been on the control of transactions, auditing mechanisms, etc. According to a key informant, since 2004 the World Bank has executed system-strengthening work in key areas such as regulatory reform and procurement in the pharmaceutical system in approximately 30 countries.

Specific anti-corruption programming has most commonly been adopted in project procurement monitoring, as in the case of India, but there are several cases in which projects themselves focus on strengthening the country's procurement policies. A two-phased, multi-stakeholder approach was launched to improve governance in the national procurement of pharmaceuticals in Uganda, Kenya and Tanzania. The World Bank is seeking to improve the flow of information that enables governments to monitor pharmaceutical procurement processes, train civil society organization representatives, assist in the creation and implementation of action plans and strengthen multi-stakeholder coalitions, all of which will ideally lead to improved pharmaceutical procurement procedures. Its five areas of focus are: (i) legal and regulatory framework; (ii) poor quantification; (iii) process gaps; (iv) institutional arrangements; and (v) disclosure of information. In Phase I, key informants found that in general there is a need to increase regional collaboration and information sharing, as well as a need to strengthen the legal and regulatory foundations that already exist in these countries in order to obtain better policies, lower prices, increase accountability among stakeholders and improve communication. With these findings the World Bank has moved into Phase II, which has included the implementation of regional workshops, electronic platforms, training and high-level policy makers' meetings to increase transparency, accountability, action planning and the sharing of information.

Key findings

Pharmaceutical good governance is addressed more generally in World Bank programmes through health system strengthening and project evaluation, which do not take a specific look at good governance dynamics in the very specialized pharmaceutical system. Where the pharmaceutical system is addressed, procurement is often prioritized, which is only one part of the supply chain. Understandably, this is the focus with the World Bank's own projects, in which procurement with World Bank funds, rather than the country processes, are monitored. However, health systems strengthening projects may have a pharmaceutical system component that involves procurement and will be monitored and enforced. Yet even with a commitment to strengthening governance and anti-corruption strategies with a sector-specific approach, there are few projects which take on the pharmaceutical sector. Part of the disconnect between governance and pharmaceutical systems-oriented work may be due to the limited institutional integration between PREM and the broader community of health specialists at the World Bank on pharmaceutical good governance, although a positive sign is the recent development of a results framework for the pharmaceutical system that includes several categories to collect data, while the benchmarking of key areas of the pharmaceutical system has been implemented at the regional level.

The World Bank has some clear strengths in its strategies for addressing good governance, as it uses a variety of strategies, an official policy on governance anti-corruption and policy and operational work in countries to ensure that its own standards are met and that countries establish systems which are sustainable once the World Bank has left. Yet even with these positives, the World Bank needs to go further. Its strategies are not applied on a uniform basis, and there is not a consistent expectation that countries practice good governance in their pharmaceutical systems. The sector-specific approach tends to focus on the health system as a whole, rather than narrowing it down to the pharmaceutical system, thus raising the question of whether such a broad approach is enough. A greater emphasis on strengthening good governance across the entire pharmaceutical supply chain is critical for preventing corruption.

4.2 The World Health Organization/Good Governance for Medicines Programme

The WHO has been actively involved in the area of pharmaceutical good governance since 2004. Good governance and transparency was first included in the 2004/2007 WHO medicines strategy, which led to the launch of the Good Governance for Medicines Programme (GGM) in 2004. The GGM understands good governance as "…the formulation and implementation of appropriate policies and procedures that ensure the effective, efficient, and ethical management of pharmaceutical systems, in particular medicine regulatory systems and medicine supply systems, in a manner that is transparent, accountable, follows the rule of law and minimizes corruption" (Baghdadi-Sabeti et al., 2009, p. 159). The programme uses a transparency assessment tool (based on the World Bank's Costa Rica methodology) first implemented in Laos, Malaysia, the Philippines and Thailand in 2005.

The GGM seeks to increase public awareness about the potential for corruption in the pharmaceutical sector, encourages anti-corruption measures in national policy making and improves integrity, transparency and capacity within the sector to maintain improvements (Baghdadi-Sabeti & Serhan, 2010). The broader goal of the WHO in facilitating the GGM is to improve access to essential medicines. The GGM was set to finish in 2012, but is undergoing an external evaluation from which further steps (such as possible continuation) will be decided.

GGM countries include:

- Phase I: Bahrain, Cambodia, Colombia, Ecuador, Egypt, Ethiopia, Iraq, Islamic Republic of Iran, Kuwait, Pakistan, Palestine, Papua New Guinea, Republic of Moldova, Sudan, Tunisia, Yemen;
- Phase II: Cameroon, Costa Rica, Indonesia, Kenya, Malawi, Morocco, Mozambique, Oman, the Former Republic of Macedonia, Zambia;[3]
- Phase III: Benin, Bolivia, Jordan, Laos, Lebanon, Malaysia, Mongolia, Philippines, Syrian Arab Republic and Thailand.

The GGM did not use a strict methodology for selecting countries. Instead, the process was based on a government's willingness to participate and the WHO's in-country capacity. Where feasible, regional representation was also a factor. Prospective participants were approached by the WHO and given the option to be part of the GGM, which was initiated in each country with clearance from the given Ministry of Health, the in-country WHO counterpart. However, close contact was also sought with civil society-, private sector- and academic institution stakeholders. One of the positives cited by informants was that it introduced concepts of transparency and accountability to a broader audience, and the WHO's member states have generally found its preventative approach to corruption appealing.

The GGM initiative is conceived to be implemented in three consecutive phases: I) transparency assessment, II) design of the national good governance for medicines framework, and III) implementation. These phases are designed in sequence so that the vulnerability to corruption, the level of transparency and pre-defined integrity indicators in the pharmaceutical system can be determined in order to design and implement appropriate measures to deal with the identified priority areas most effectively. Moreover, the length of these phases is variable depending on a country's circumstances.

Phase I consists of an assessment of the transparency of the pharmaceutical system, defined as a "openness in sharing information and that information is publicly and easily accessible for those who need it" at the different decision points of the pharmaceutical system, as well as the vulnerability of each decision point to corruption (Baghdadi-Sabeti & Serhan, 2010). Countries entering the programme have successively assessed more areas of the pharmaceutical system as the programme has grown, and the assessment tool now includes: i) clinical trials, ii) manufacturing, iii) registration, iv) licensing, v) inspection, vi) promotion, vii) selection, viii) procurement and ix) distribution (Baghdadi-Sabeti, Kohler, & Wondemagegnehu, 2009). The assessment employs a mixed method, with both quantitative and qualitative indicators (semi-structured interviews) being executed by national assessors, who are usually identified by the Ministry of Health. The questions deal with institutional structure and processes indicators and the extent to which each of the key informants is aware of the existence and application of these, whereas other questions capture key informant's perceptions regarding the transparency of select processes. Given the focus on vulnerability to corruption, it does not include hard data on access to medicines or a counterfeit share of the marketplace. The questions are focused on the public sector actors, but less so on non-state actors such as the private sector, NGOs, etc. The tool has also been adapted to a national context to ensure its relevance to the specific pharmaceutical system function (Baghdadi-Sabeti, Kohler, & Wondemagegnehu, 2009).

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[3] In December 2012, Malawi and The former Yugoslav Republic of Macedonia approved their national framework and entered into Phase III.

Figure 2: Good Governance for Medicines, assessment tool rating system

0.0 – 2.0	2.1 – 4.0	4.1 – 6.0	6.1 – 8.0	8.1 – 10.00
Extremely vulnerable	Very vulnerable	Moderately vulnerable	Marginally vulnerable	Minimally vulnerable

Table by Baghdadi-Sabeti, Kohler, and Wondemagegnehu:
"Measuring Transparency in the Public Pharmaceutical Sector: Assessment Instrument", 2009, 16.

Figure 3: Good Governance for Medicines, phase I results
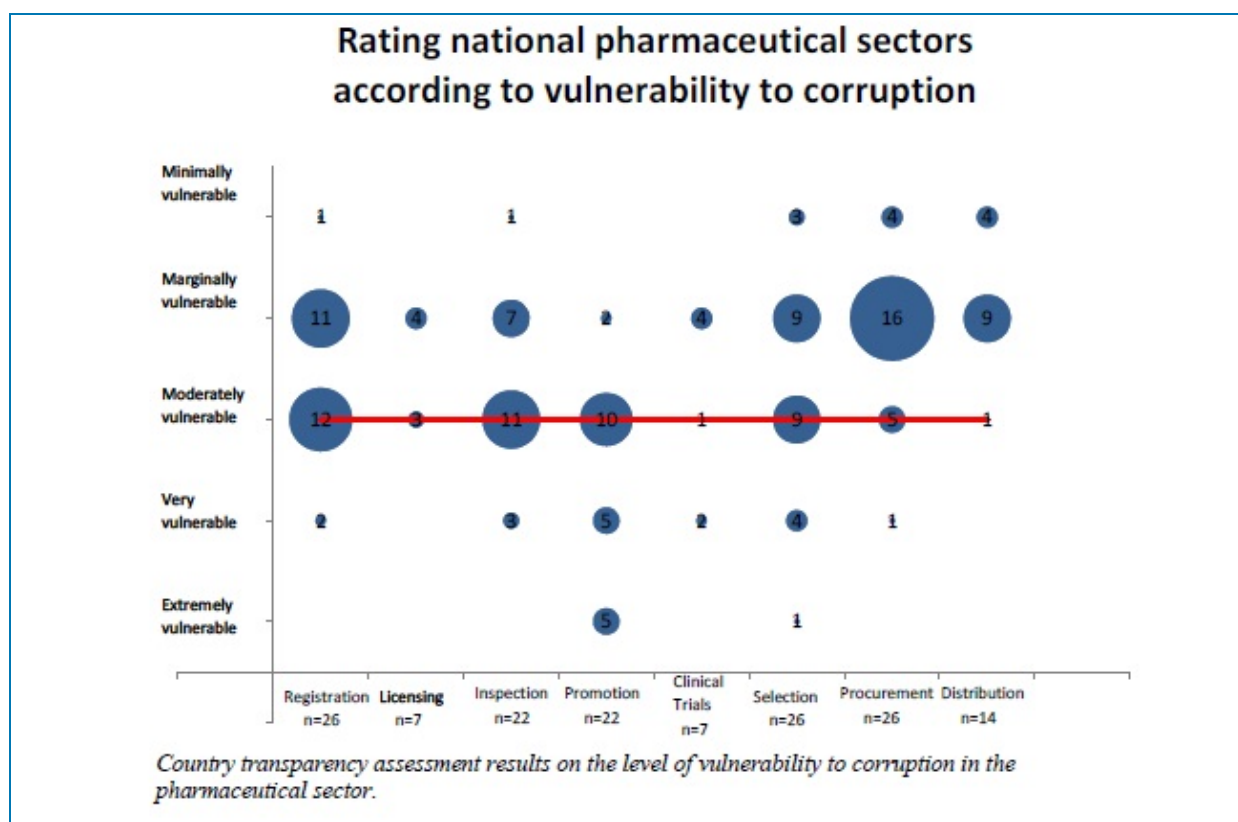
Graph by Baghdadi-Sabeti and Serhan:
"WHO Governance for Medicines Programme: An innovative approach to prevent corruption in the pharmaceutical sector", World Health Report Paper 25, 2010.

Phase II uses the results of Phase I- and stakeholder consultations to draft a national good governance for medicines framework. This is the stage in which a national Good Governance for Medicines Task Force and at times a Steering Committee (nominated by the Ministry of Health) are established, which helped to develop the framework (code of conduct, promotion of moral leadership and anti-corruption legislation, as well as mechanisms for whistle-blowing), in addition to managing the implementation of the programme (World Health Organization, 2009). This process may include outcomes such as a national GGM workshop, an effort to implement good governance initiatives based on the findings from the assessment, a consensus-building workshop on promoting ethical practices and a draft of a national ethical infrastructure. The foundation of the framework is the combination of a disciplines-based approach and values-based approach to good governance (Anello, 2009). The values-based approach includes a system of moral values and ethical principles, a programme for the systematic

socialization of the moral values, ethical principles, code of conduct and the promotion of moral leadership. The disciplines-based approach includes anti-corruption legislation, mechanisms for whistle blowing (ombudsman), sanctions on corrupt acts based on anti-corruption legislation, and within the pharmaceutical system established management procedures that include internal and external financial audits, collaboration between anti-corruption agencies, civil society organizations, the private sector, management, coordination and the evaluation of the good governance programme (Anello, 2009).

Phase III of the GGM is the implementation of the national framework, which includes the development of any procedures, legislation, conflict of interest policies and codes of conduct as determined in the previous phases. There is also an emphasis on training with the core values and principles of good governance and raising awareness within the population on the issues. Incorporating a broad range of stakeholders, including the Ministry of Health, private sector- and civil society representatives, the GGM created an opportunity for stakeholders to go beyond a basic discussion about transparency in order to move towards a clearer understanding of the extent of the conditions that needed to be addressed to ensure good governance. In other words, the GGM sought to understand the pharmaceutical system's current conditions, processes and outcomes, and identify strategies for their improvement.

The GGM established numerous support mechanisms for participating countries to assist with the implementation and facilitation for exchanges of the lessons learned. Collaboration with other initiatives was recommended for participating countries in the Good Governance for Medicines Model Framework, although in practice this has been somewhat limited (Anello, 2009). The WHO set up a group of experts in the fields of medicine, public health and anti-corruption to advise countries and to help ensure the sustainability of GGM initiatives (World Health Organization, 2010). It also helped to facilitate the networking opportunities for participating countries. These are venues through which countries at similar phases of the GGM shared good practices and helped each other identify solutions to the common problem of corruption.

The WHO is currently undertaking its own examination of the impact of the GGM, with an assessment of 15 country reviews conducted in 2011with the support from the World Health Organization Alliance for Health Policy and Supply System Research. Based on annual country reporting, the analysis is meant to be used by countries as an indicator of whether different initiatives are working, in addition to highlighting sound evidence in policy formation (Hamra et al., 2011). The study found that the biggest gains from participating countries were improvements to registration, drug selection and procurement. At least 60% of countries displayed improvements in registration by creating an updated list of all registered pharmaceutical products, completing written procedures for submitting registration applications and creating formal committees with written criteria for member selection responsible for registration. Improvements in drug selection included the creation of Selection Committees with written criteria and expert members from different fields, conflict of interest declaration forms, standard operating procedures and clear terms of references. Thirteen countries improved their procurement practices by strengthening transparency procedures such as bidding processes and tender advertisement, as well as by implementing guidelines for procurement methods of various types of products, formal appeal processes, systems for monitoring and reporting on suppliers' performance and regular audits (Hamra et al., 2011). The findings are limited because not all participating countries completed the same "decision points" in the transparency instrument since they entered the Programme at different times and the instrument had been modified. The assessment is an initial examination of the GGM that will ideally inform the next phase of the programme.

Key findings

The WHO has noted that some of the challenges encountered while implementing the GGM are generalizable to any governance initiative in the pharmaceutical system. These include potential

obstacles linked to culture and behavioural factors (for example, gift giving may be perceived as a "normal" business practice), resistance to change, a lack of political commitment and a lack of resources to effectively implement a GGM initiative (Baghdadi-Sabeti & Serhan, 2010).

Country ownership, both through political commitment and broader societal participation, is particularly critical to the GGM and is achieved through multiple approaches. The programme actively promotes the leadership of the Ministry of Health and seeks its buy-in for the initiative (Anello, 2009). Nevertheless, there are challenges to maintaining this support, as there may be a change in government or early support that may not have included the Ministry of Finance or other relevant institutions involved in the pharmaceutical system. The transition from Phase I to Phase II is the most challenging according to key informants and the most vulnerable to political changes and withdrawal of support from new officials, which may lead to disruptions in GGM implementation. Including civil society and the private sector allows for multiple viewpoints to be considered in the development of good governance practices, with the ultimate aim of positive and sustainable results. The GGM also leaves room in the initial transparency assessment for an adjustment to better reflect the country context, which is important to the buy-in from stakeholders.

While critical for the GGM's success, the involvement of the Ministry of Health may be too inclusive in terms of the assessment methodology. Currently, the Ministry of Health appoints the persons who are responsible for implementing the tool, and the assessment is largely based on perceptions, giving rise to impartiality concerns due to the relationship between assessors and the Ministry of Health, which could lead to the former being careful of how far they probe in different areas of questioning. This could potentially result in limited probing to avoid an uncomfortable detection of information. Anecdotal evidence suggests that some of the findings from the GGM assessment tool, which are published in WHO country studies, are not always consistent with the observed weaknesses of some of the pharmaceutical functions examined. Given this, the WHO is now recommending that national assessors be independent from their respective Ministry of Health. The challenge with ensuring assessor impartiality suggests that there is a need for more rigorous grounding in empirical data.

While the WHO aims to work with GGM countries on implementing good governance initiatives, it has limited expertise in this area, thus resulting in individuals with more general experience in the pharmaceutical system being involved in good governance work. Because governance in the pharmaceutical sector is at the interface of political/health/pharmaceutical science, experts in this area are typically strong in one particular area. Ideally, a cadre of health experts will become more experienced in governance issues, and there has also been a limited collaboration with other international actors in GGM initiatives (outside of those countries where MeTA is involved). This may be attributed to the fact that there are not many donors working specifically on pharmaceutical good governance, which suggests that the WHO needs to more actively seek out partnerships in this area with donors working on related areas such as health-care systems strengthening.

4.3 Medicines Transparency Alliance

The MeTA was established by the DFID with technical support from the WHO and the World Bank in 2008, with the aim to improve transparency and accountability in the pharmaceutical system in order to have a positive impact on access to medicines (MeTA, 2012). It was piloted from 2008-2010 in seven countries: Ghana, Jordan, Philippines, Kyrgyzstan, Peru, Uganda and Zambia and is now in Phase II (2012-2016). Furthermore, the seven chosen countries formed a large and diverse pilot programme (Ollier et al., 2010).

MeTA projects were initiated with a formal commitment by the participating government, an agreement on a core set of principles and the development of a national multi-stakeholder group. Individual country work focused primarily on data disclosure and transparency in data collection and dissemination in the following areas: i) quality and registration status of medicines; ii) availability of

medicines; iii) price of medicines; and iv) promotion of medicines (MeTA, 2008). Disclosure was to include information on current policies, practices and outcomes, and country context information has been critical to the countries and includes information about system operations, the affordability of medicines, equitable access and the rational use of medicines through baseline surveys. Another critical component was the strengthening civil society in order to build an advocacy base, which would ideally serve as a catalyst to encourage the government to implement changes in line with the MeTA.

The development of multi-stakeholder groups was a core part of the pilot and continues to be important in Phase II. The MeTA seeks to bring together stakeholders from across the public sector, private sector and civil society and to build trust among them, thereby allowing for an open discussion and cooperation with regard to MeTA objectives. The group is responsible for developing country work plans and overseeing the implementation of action items (MeTA, 2012).

During the pilot phase, the MeTA was solely funded by the DFID, which channelled resources to the World Bank and the WHO for implementation and technical support (Ollier et al., 2010). The MeTA's initial structure was complex, with different management groups at both the international and country levels. Internationally, there are three important groups: the International Advisory Group (country representatives and international experts), the MeTA Management Board (administration and funding: DFID, WHO, World Bank) and the International MeTA Secretariat (contracted to manage implementation: Health Partners International, HERA, and Healthlink Worldwide[4]), while at the country level there is a biannual meeting of a MeTA forum, a MeTA Council (the multi-stakeholder alliance that guides the country strategies) and a national MeTA Secretariat in charge of the implementation (MeTA, 2010a). In response to findings from an outside review commissioned by the DFID ("the Review") about top heavy governance, significant changes have been made to simplify the structure. Since 2011, funding has been directed to the WHO and Health Action International (HAI), which are also fulfilling the role of the International MeTA Secretariat, as the need for a Management Board no longer exists.

Figure 4: Organizational structure of MeTA in phase I
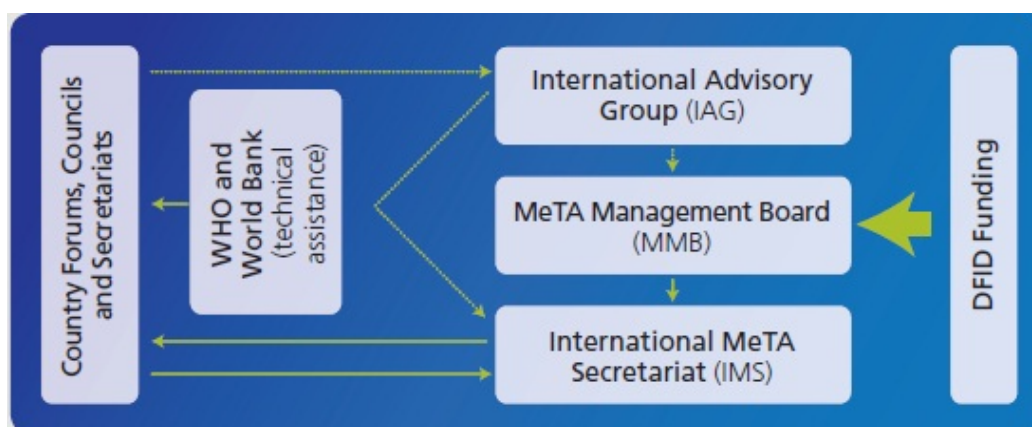
Diagram from: Medicines Transparency Alliance, 2012; A Review of the Pilot

As stated above, the pilot required the establishment of a multi-stakeholder group in each country, including representatives from the public sector, private sector and civil society. This group led the process of preparing baseline surveys that ideally would be used over time for monitoring and evaluating the progress of the MeTA. The survey had three primary components: (1) An inventory of existing pharmaceutical sector data that was made publicly available; (2) a data disclosure survey; and

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[4] Healthlink Worldwide stopped its operations in 2011.

(3) a quality assessment of the multi-stakeholder processes, the last of which was done towards the end of the pilot. All of the countries completed the first two components and five completed the third, in addition to developing work plans that focused on strategies for data disclosure. Although the Review noted that all the countries completed the baseline assessments, not all of the information was publicly available or initially reported. Part of this lag was due to the fact that the surveys took longer than anticipated, and in most cases were completed after work plans had been developed and information gaps identified (MeTA, 2010b).

The MeTA work plans were clearly shaped by country context and individually established national strategies, which can help explain why there are very few similarities between the countries. There was a broad consistency in terms of incorporating strategies for civil society organizations, capacity building and data disclosure, though the actual action points varied greatly. For example:

- Zambia: Increase availability and access to paediatric formulations (Nshindano, 2009).
- Uganda: Conduct quarterly medicines price monitoring surveys to be made public and disseminated; increase awareness in communities on rational drug use (MeTA, 2009d).
- Kyrgyzstan: Develop information systems to guide decisions (including information on registration, licensing, the certification of imported drugs and more); conduct survey of accessibility of State Guarantee Programmes (particularly the impact on the health of patients with asthma and psychiatric disorders) (MeTA, 2009c).
- Philippines: Proactive use of the data disclosure survey as evidence for policy makers to help create transparent and accountable processes for medicine selection, registration, procurement and use (only country with baseline surveys as the key goal) (Abueva, 2011); improve regulatory and quality management departments.
- Ghana: Conduct medicine quality studies using the German Pharma Health Fund minilabs; publicly disclose the national health insurance scheme data (MeTA, 2009a).
- Jordan: Increase evidence-based decisions related to the Rational Drug List; improve procurement and system (Bader, 2008).
- Peru: Organize a citizen-monitoring network; prepare methodology, data sources and data exchange mechanisms between institutions (MeTA, 2009b).

Now in Phase II, MeTA is emphasizing country-level work, setting more concrete goals and implementing programmes based on baseline survey results (UK Department for International Development, 2012). There is a concern that the baselines only provide a limited "snapshot" of the identified problems in the various country systems. To allow for a more comprehensive and current understanding of the dynamics of pricing and drug availability in a given pharmaceutical system, the WHO and HAI are developing new tools to allow for the regular updating of medicine prices and availability at the facility and pharmacy level for more consistent tracing. Another important response to pilot challenges is the establishment of entry and exit criteria. The exit criteria include the requirement that country work plans be approved by the International MeTA Secretariat prior to programme implementation.

Key findings

The MeTA has largely made gains in the development of multi-stakeholder groups, the development of pharmaceutical system baseline analyses and in the creation of opportunities for the global exchange of information. The country pilots did not all have the same objectives in their work plans, which may be attributed to the various goals and targets of MeTA (Ollier et al., 2010), as well as the importance of country context in terms of defining strategies to suit the features of each pharmaceutical system. The MeTA also provided countries with a "customizable" methodology, but there has been some consistency in the completion of the first two baseline surveys in each country,

which is positive insofar as it gave flexibility to the programme while ensuring that comparable data was collected. Although the MeTA has helped foster global information exchange on areas relevant to good governance in pharmaceuticals, mechanisms for sustainable information flow have not yet been created.

The MeTA pilot was considered to be the initial test of the hypothesis that increased transparency, and that multi-stakeholder collaboration would lead to an improved access to medicines. At the end of Phase I, the MeTA was unable to assess whether there had been an improved access to medicines in all countries, and has now moved into Phase II, though with some clear differences in approach from the pilot. There was a delay before the start of Phase II that left some countries feeling isolated in the process, which was a concern in terms of maintaining momentum (DFID, 2012). In Phase II, the MeTA will clearly need to focus on determining its impact on access to medicines and on ensuring the sustainability of the programme.

The pilot had many soft outcomes such as the engagement of key stakeholders for a more inclusive dialogue about pharmaceutical policy. In fact, the multi-stakeholder system was most consistently reported as its greatest strength since it brought together stakeholders who otherwise would have had little communication, as it is a concern that the composition of the multi-stakeholder groups varied across countries. For example, representatives from the private sector were more prominent in Jordan, as civil society groups were not plentiful at the inception of the MeTA pilot. Another important finding was that if the group size was too large, its effectiveness was limited because discussions did not turn on specific issues, but rather on broad ones that were too ambiguous to be helpful (MeTA, 2012).

Many key informants did note that it was too early in the MeTA process to determine the more difficult outcomes, which was not helped by the fact that the MeTA's mission was ambitious in terms of what could be delivered. The initiative needed to establish trust among the key stakeholders in the MeTA Councils, a necessity for the promotion of transparency, but one that takes a significant amount of time. While there were clear outputs, such as the completion of baseline surveys and data disclosure, it was difficult to link these to other results such as drug pricing policy changes or a reduction in drug prices for tracer drugs.

The MeTA generated data on the pharmaceutical sector using standardized tools in the baseline analysis intended to produce robust data so that the multi-stakeholder group could then develop responses for improving transparency, including support from the International MeTA Secretariat to help with the identification of possible causes and policy responses based on international experiences. Ideally, country work plans would then evolve with a more detailed analysis and data collection activities targeted to those areas where problems were identified, but the very broad range of actions outlined in the work plans may have been too wide an approach, as it may have been more effective to encourage countries to be more focused on the goals set in the work plans or to use more targeted tools from the outset (e.g. procurement audits). In light of this, Phase II is pursuing the implementation of policy responses based on pilot data, though with a stronger focus on prioritizing issues that target transparency, as well as developing tools to more often track changes in performance.

The effectiveness of the governance structure was found to be limited, both in the MeTA Review and in key informant interviews, hence affecting the work being done in the pilot countries. Part of the initial challenge was that the participant organizations in the MeTA Management Board had different understandings about their roles within the MeTA process, in addition to the purpose of the initiative. The lack of clarity on the mandate of the MeTA initiative at the international level also translated to a lack of clarity at the country level. This is being addressed in Phase II, with one of the conditions for the work plan approval being that there is a connection between the proposed programmes and increasing transparency.

The Review also points out that the MeTA Management Board spent much of its activities on monitoring the International MeTA Secretariat and little on stewardship, thereby putting into question who was providing the countries with guidance (Ollier et al., 2010). Although the International Advisory Group was meant to guide and support countries, the MeTA Review states that the actual role of the International Advisory Group was never clarified and that it acted largely as a board. In part, this was because during the pilot the DFID ensured that the MeTA Management Board controlled the process and was unwilling to allow the International Advisory Group to assume significant control in the process. Weak communication between the in-country- and international level groups resulted in MeTA Councils being unaware of the resources available to them. These governance challenges in the MeTA highlight the importance of the initiatives having clear goals and streamlined approaches.

In some cases, it is difficult to identify the results from MeTA, including those that would have happened even without it being due to other initiatives such as the GGM (MeTA, 2012), although to be sure the GGM and MeTA overlapped their operations in the Philippines, Zambia and Jordan. As described in the Appendix, both projects were able to undertake different activities quite successfully in the Philippines, while in Zambia the GGM did not achieve its goals. And in Jordan, given that the GGM did not have funding, it worked more closely on the MeTA activities (see Annex for more information). Even with the challenges of evaluation due to programme overlap in the MeTA and GGM, the results in the Philippines highlight the benefits that can be attained when there is cooperation between initiatives with similar goals. The two programmes were aware of their complementary mandates, but operated in such a way that they each addressed the aspects of the pharmaceutical sector to which their initiative was best suited.

4.4 The Global Fund to Fight AIDS, TB and Malaria

The Global Fund was founded in 2002 through a public-private collaborative effort conceptualized by members of the G8 in 2000, forming a non-profit organization with the Swiss government. The Global Fund is an independent organization based in Geneva – a public-private partnership between international organizations, countries, corporations and non-government organizations – funded by donor countries (Global Fund, 2003). Its original mandate was to act primarily as a funding agency for developing a country programme targeting the "big three" diseases in its title (Global Fund, 2003). A key component of its strategy is to encourage country ownership by establishing "Country Coordinating Mechanisms" (CCMs), which manage the application and disbursement process in each country. It provides grants to a number of recipients in developing countries that represent a broad range of organizations, including the public sector, private sector, government, non-governmental organizations and academic institutions and groups.

Pharmaceutical procurement is a crucial part of the Global Fund's activities; an estimated 40% of grant funds are allocated for the purchase of medicines. The Global Fund oversees procurement by its country beneficiaries, and aims to ensure that it includes transparent procedures with defined competition processes for all recipients. Procurement is focused on gaining the lowest price and suppliers, and monitoring reports with details on prices and quality are submitted to its Price & Quality Reporting Mechanism (Global Fund, 2009). The procurement of pharmaceuticals is regulated by each recipient country's national drug regulatory authority and follows good practices for drug registration of pharmaceutical products. The required practices differ based on the type of medicine procured but always include approval by the relevant national authority, while quality assurance is ensured through a complete Global Fund quality assurance policy, not only through quality control testing (Global Fund, n.d.).

Funds are directed at the project level, which are often reviewed by a panel to determine how to best make the project sustainable; this may or may not include integration into other existing structures (High-Level Independent Review Panel, 2011). Furthermore, country recipients are responsible for submitting and enforcing the procurement plans submitted, which follow the interagency standards as

expressed in the Operational Principles for Good Pharmaceutical Procurement and A Model Quality Assurance Supply Chain for Procurement Agencies (Global Fund, 2009). The procurement plan should ideally include how these standards will be adhered to, such as which institution will implement procurement, technical assistance needs, other relevant sources of funding, details of the procurement and supply management cycle, key health products and total cost, total cost of ownership for durable products/storage and distribution costs (Global Fund, 2009). The Global Fund recommends to country recipients that random samples of procured medicines be taken from different parts of the system for quality testing at either WHO Prequalified or ISO 17025-accredited facilities (Global Fund, 2009).

The Global Fund has developed a code of conduct for its suppliers, but makes it the responsibility of country team members such as principal and sub-recipients, CCMs, procurement agents and first-line buyers to ensure that suppliers are informed about it. The code of conduct forbids corrupt practices and expects transparent and accountable processes, in addition to demanding compliance with laws and regular reporting as well as appropriate action from grant recipients if they become aware of inappropriate practices. Conflicts of interest must be declared, and participants must agree with the United Nations Global Compact for corporate citizenship.

Local Funding Authorities, which are independent agencies such as Pricewaterhouse Coopers, KPMG or Crown Agents, evaluate country plans and determine if the country has the capacity to manage the procurement. They then make recommendations to the Global Fund about how to best proceed with procurement, e.g. they may recommend contracting out parts of the procurement process.

Given that the procurement of pharmaceuticals is technically complex and that guidelines are difficult to follow when countries do not have sufficient technical capacity, the Global Fund does offer some support to country recipients. These include specific agency support for multi-drug resistant tuberculosis procurement and the more general Voluntary Pooled Procurement (VPP), which was established in mid-2009 for the purchase of key health products (Global Fund, 2011).

Although VPP is not mandatory for recipient countries, it has been recommended that it should be a default process for procurement (or other external purchasing channels) due to the risks of weak domestic procurement policies, i.e. countries would automatically use VPP unless they present a case for exclusion (High-Level Independent Review Panel, 2011). Currently, when grants are reviewed, including procurement capacity, VPP is often proposed as an option for high-risk countries. However, because the use of this mechanism is seen as a way to protect themselves from future accusations of fraud, non-high risk countries often request to use it as well. From June 2009 to December 2010, US$502 million was spent on Voluntary Pooled Procurement by the Global Fund. From 2009 to 2011, VPP has accounted for US$57 million in aggregate savings (Global Fund, 2012). It is estimated that the value of pharmaceuticals procured through the programme will amount to US$400 million in 2013, which is 30% of all Global Fund-funded procurement.

Key findings

Despite the Fund's efforts to ensure best practices in the pharmaceutical systems of its country recipients, in October 2010 the Office of the Inspector General found evidence of fraudulent practices in a number of Fund-beneficiary countries, including Djibouti, Mali, Mauritania and Zambia. In view of this, the Fund demanded a recovery of US$34 million (out of US$3 billion in disbursed funds). These incidents gained a public profile when the story about the fraud was reported in the international media (Heilprin, 2011), with some countries suspending funding. The Fund was subsequently on notice that it needed to take significant actions to better guarantee good governance.

In 2011, the Global Fund initiated a High Level Independent Review ("Review") that took place over six months to evaluate the functioning of the organization, which examined the overall structure and

functioning of the Fund and covered specific topics relevant to pharmaceutical good governance. These sections are highlighted below, as they are helpful in terms of understanding the strengths and weaknesses of policies and processes that relate to the issue of good governance in the pharmaceutical system (High-Level Independent Review Panel, 2011).

The Review found a number of weak areas in the pharmaceutical systems in countries, some of which could lead to corruption. For example, the Local Funding Agents did not always have the expertise required to undertake proper monitoring of the drug supply system. There were additional areas of weakness that included: inadequate forecasting, poor procurement processes, and insufficient quality and safety standards. For example, storage conditions were weak and there was little oversight. Even when procedures were in place, responsibility was often given to individuals with insufficient expertise (High Level Independent Review Panel, 2011). And there were as many as 17 cases of drug theft in 13 countries in Africa under investigation by the Office of the Inspector General of the Fund (High Level Independent Review Panel, 2011).

One of the major policy issues facing the Fund is whether it helps or hinders pharmaceutical/health system strengthening. Some of the literature emphasizes that if the Fund grants result in procurement that is integrated into existing systems, improvements will happen in procurement as well as the overall health care system (Bennett and Fairbank, 2003). On the other hand, if the grants are managed as vertical programs, they may actually hurt existing systems by not addressing local capacity needs (Bennett and Fairbank, 2003). The case of a Global Fund grant in Malawi presents both of these situations. UNICEF managed the procurement of antiretrovirals in Malawi so there was no local capacity building. However, the malaria drug procurement process was managed by a combination of public and private (previous partnership) procurement, which one study viewed as a positive outcome (Mtonya & Chizimbi, 2006).

The activities the Global Fund undertakes on pharmaceutical systems are usually limited to securing the proper procurement of grant-funded medicines. While quality testing is performed, comprehensive reviews of each health facility receiving medicines are not undertaken, and it is also unclear how well the code of conduct is being enforced at the country level since it allows for a liberal interpretation of the content and effectiveness is not monitored. If countries choose to use VPP, no pharmaceutical system strengthening takes place, although it may very well be more efficient for a country with a small population to subcontract VPP. The Global Fund aims to minimize the risk on its own projects, and in this regard, country ownership is not as difficult to establish as it may be in other initiatives. There is little political resistance from governments because funding is dependent on pragmatic changes, not long-term changes, and potential recipients understand that receiving funding is contingent on cooperation with changes. If present, resistance to change is more likely to be found downstream where implementation takes place.

Collaboration does occur with other organizations. For example, multiple countries work with the Clinton Foundation or the President's Emergency Plan for AIDS Relief to assist in the quantification of need for procurement. Outside organizations are able to support grantees through corresponding projects that strengthen health systems and by providing additional funding (i.e. six countries fund the Millennium Development Goals Fund, which provides flexible resources for strengthening systems and other issues).

In short, the Global Fund is a major global supplier of medicines and the importance of ensuring robust pharmaceutical systems in beneficiary countries and between the Global Fund and recipient countries is obvious. A recent examination highlighted that despite efforts to ensure good governance in procurement, there are many weaknesses apparent in the pharmaceutical systems and limited measures to address them.

5. Conclusions and lessons learned

Based on the findings above, we make some preliminary conclusions and close with recommendations for both policy makers and donors. The focus of these leading international initiatives on pharmaceutical good governance is positive insofar as recognition is being placed on a pervasive problem in the health-care system so that improvements in pharmaceutical good governance, and ultimately access to medicines, can take place.

There is a perennial tension in all of the examples described, as system change is needed, which takes time, capacity and a broad commitment to implement initiatives and to determine the results from them. More focused efforts on specific issues (e.g. drug registration or public sector generic substitution policies) can result in more rapid changes, but may not result in the deeper systemic change needed to improve overall system performance. Additionally, it is always important to situate the pharmaceutical sector within the context of the broader health-care system dynamics, along with economic and political perspectives. No approach is necessarily "comprehensive" enough at any single point in time. Efforts must be iterative, making changes when needed and also changing the focus over time, in part because any change will result in different incentives and new opportunities for corruption.

To be sure, the pharmaceutical good governance initiatives identified have been particularly useful in generating much needed political and policy dialogue around a crucial health issue among stakeholders who had generally not come together before. The multi-stakeholder groups of the GGM and MeTA have generally been assessed as a positive outcome. These initiatives are valuable insofar as they identify weaknesses in the pharmaceutical system and provide an important baseline of data (however imperfect it may be). By developing these baselines, concrete remedial strategies can be developed. Nonetheless, it is also apparent that there is often a significant gap in countries between the identification of problems, the strategic design to address problems and implementation.

The data collection tools used are often focused on procedures and standards that are assumed to prevent corruption practices, primarily focussing on the rules, procedures and perceived practices in place for public sector actors. The tools used seem cumbersome and are not designed to examine the complex dynamics that lead to corruption; namely, the interaction and relationships of all stakeholders and how the private sector, civil society and relevant institutions outside of the Ministry of Health use or abuse the rules, procedures and practices.

One of the long-standing weaknesses of many global funders has been a lack of attention to pharmaceutical good governance prior to granting loans, as the transparency and accountability of the pharmaceutical system in country system operations is vital. Without it, the effectiveness of investments in the health systems and the integrity of programme funds are in peril, as was the case for the World Bank and Global Fund.

A vital omission in all of the pharmaceutical good governance initiatives, whether by design or oversight, is the lack of attention given to the political dimensions of pharmaceutical good governance. While an initial buy-in from governments is ensured, the tools themselves evade examining how political issues such as state, regulatory and policy capture-, as well as how institutional competition impact, pharmaceutical good governance. This also includes developing strategies and tactics to gain the continuous political commitment of governments. By choosing to omit the political economy of pharmaceutical good governance, the prospects of meaningful outcomes are limited.

A surprising finding among all of these initiatives is the little attention paid to the design and establishment of monitoring and evaluation systems. There is a need to design monitoring and evaluation mechanisms not only for the process of the initiatives, but for their expected results, e.g.

measuring whether drug price information is more available and how much drug coverage has improved as a result of these initiatives. Without this, it is very hard to judge the value of these efforts, thus causing a limitation in the results to "soft" outcomes. What is promising is that the MeTA will focus on this area in Phase II.

Moving forward, further lessons for consideration are:

1. Donors need to promote political dialogue and stakeholder consensus building throughout the implementation of initiatives to agree on priority areas within the pharmaceutical system, as well as on which tools are most effective to employ.

2. Granting institutions such as the Global Fund and the World Bank should leverage their resources by providing funding to countries when good governance is in place or when a commitment has been demonstrated to address governance weaknesses and to withhold resources when these conditions are not in place. Given that measuring good governance is not yet a standard government practice, this would likely require the development of a pre-approval analysis of pharmaceutical systems, which should include both empirical measurements and a broader consideration of the local regulatory and political dynamics.

3. Monitoring and evaluation mechanisms need to be an essential component of any governance initiative. Moreover, we need to move away from a reliance on irregular surveys and move towards a better use of routine information and more "real" time sampling methodologies that can generate data to inform management decisions and sustain advocacy and vigilance by community groups.

4. Country ownership of pharmaceutical good governance initiatives is critical, which includes political support and the facilitation of a dialogue with a range of local stakeholders to ensuring that they are a part of programme development and implementation. This has been an integral to the success of countries such as Jordan and the Philippines, in both the GGM and the MeTA,

5. Grant-making institutions should pay more attention to making sustainable improvements in country pharmaceutical supply systems and the regulatory environment that governs them instead of on the execution of individual grants.

6. Donors need to ensure a "top-down" and "bottom-up" approach to good governance. Ideally, champions within government should be identified and supported by the vigilance activities of reputable non-government organizations, community-based organizations and companies that have an interest in a rules-governed market.

In conclusion, the pharmaceutical good governance initiatives discussed have had the most value in generating a greater awareness about the issue, and in some instances have implemented important sector-specific governance initiatives. The World Bank has specifically made gains in the procurement area and on general health systems strengthening, which also has some benefits for pharmaceutical systems. The WHO has helped raise awareness on the importance of good governance and initiating a critical good governance policy dialogue in many countries. Furthermore, the MeTA has created important multi-stakeholder alliances and conducted pharmaceutical system baseline analyses, which provide much needed data in some areas in relation to any further efforts. And lastly, the Global Fund is promoting "best practices" such as Voluntary Pooled Procurement, though as we have found, there is a considerable amount of space for the improvement of international initiatives to help ensure more meaningful results. Critical recommendations include the need for political analysis, monitoring and evaluation, particularly with regard to the measurement of results and the streamlining and uniformity of assessment tools across institutions.

Annex I: Country examples

Jordan

The World Bank, the MeTA and the Good Governance for Medicines Programme have all been active in Jordan with regard to pharmaceutical good governance. The Jordanian Government was open to pursuing a MeTA and Good Governance for Medicines project, as it was in accordance with its current strategy of pursuing exports for regional and world markets. The World Bank was willing to work in Jordan since it was already involved in efforts to improve the pharmaceutical system through an existing health-care project that included a component on pharmaceutical laboratory quality control. Under the MeTA, there was a Memorandum of Understanding between the Ministry of Planning and International Cooperation. The High Health Council held the Chair of the MeTA Council, while the Good Governance for Medicines Programme was under the purview of the Jordan Food and Drug Administration. As Phase II of the MeTA begins, it is now also based in the Food and Drug Administration. Jordan was regularly praised as one of the most successful countries in both the MeTA and Good Governance for Medicines. It has reached the final stage in Good Governance for Medicines and managed to get concrete results through the MeTA pilot, even with a short deadline. These included the development of conflict of interest policies in the Food and Drug Administration through Good Governance for Medicines and the beginning of the establishment of treatment guidelines through the MeTA. Much of the success in Jordan was attributed to the government's support and openness to implementing the initiatives. Even when there was a change of the Minister of Health, there was no significant impact on the initiatives, which helped to ensure some clear outcomes.

For the MeTA, the focus in Jordan is comprised of improving treatment guidelines and improving procurement practices, which ***included establishing what prices were being paid for drug procurement. Finding out what prices were paid was challenging but achieved, alongside the introduction of a monitoring system. Efforts were also placed to improve medicine selection and the rational use of medicines. For example, a Committee on *"Improving Rational Use of Medicines,"* was formed and worked on consolidating and implementing Standard Treatment Guidelines. The Committee reviewed existing standards and conducted a gap analysis. There is on-going interest in implementing the Standard Treatment Guidelines in Jordan because they are part of the requirements for hospital accreditation that is taking place under a Jordan-USAID health systems project. Jordan had good stakeholder involvement in the process and was particularly good at ensuring private sector representation and also helped foster more civil society participation on the issue. Jordan is now in Phase II of MeTA and pursuing a range of initiatives. The proposed work plan was developed by six subcommittees and its focus includes: developing policy recommendations for the rational use of medicines, pricing regulation, disclosure policy and national drug policy, developing systems and training for procurement estimations to improve inefficiencies and cost containment; assessment of the feasibility of a monitoring system for price and availability; increasing voice of civil society, and civil society educating citizens on patients.

Collaboration between MeTA and Good Governance for Medicines was strongest in Jordan out of the three countries reviewed in more depth. For one, the membership of the Good Governance for Medicines Committee and the MeTA Council was largely composed of the same members (except for two persons). The programs had started at different times and the driving groups wanted to maintain ownership over the projects. Nevertheless, they did build on each other's progress. Good Governance for Medicines principles were promoted in MeTA's implementation. For example, MeTA made use of standard operating procedures of civil society engagement suggested by Good Governance for Medicines. On the other hand, the Good Governance for Medicines benefited from MeTA by using its momentum to advance the Good Governance for Medicines Programme. Good Governance for Medicines was encouraged to make use of MeTA's in-country studies, which resulted in many synergies and complementarities between the two initiatives that without a doubt contributed to

Jordan's many successful changes to their system. In comparison to MeTA, the Good Governance for Medicines had wider involvement of ministries outside of the health sector, the media, as well as interactions with the Jordanian Anti-Corruption Commission.

The Philippines

The Philippines has a highly decentralized pharmaceutical system, which meant that initiatives in the country had to consider what was appropriate to undertake nationally and regionally. The national government was supportive of MeTA and Good Governance for Medicines, the former Minister of Health even served as MeTA's Council Chair from 2008 to 2010. However, even with this in-country support there were challenges in implementing the initiatives. Even with political support, its impact was limited because of the system's extensive decentralization. The points of vulnerability (e.g. procurement) in the system were downstream. It was beneficial that MeTA focused more on the national policy level and Good Governance for Medicines on the downstream level.

Based on the baseline surveys, MeTA focused its efforts on pricing and availability, mark-ups/components of pricing, procurement, national drug policy, stakeholder engagement (qualitative), and practices in the marketing of pharmaceutical products. Although data collection had been done in the health sector before, MeTA provided more rigorous and targeted methodologies for baseline data collection. At the end of the pilot, MeTA played a role in the passing of new legislation on affordable medicines. A problem that MeTA faced in the Philippines and elsewhere was a high lead-time that was required to complete surveys and a timely process to disseminate the information. Many of the key informants expressed that the timeframe for MeTA was short (two years) thus the possible results were limited. Most noted however that the baseline surveys of the pharmaceutical system by MeTA were helpful insofar as they led to consensus on problems in pricing and access, but the subsequent process of developing solutions did not work as anticipated.

Stakeholder engagement was positive. In the beginning the public sector was suspicious to engage in dialogue with the private sector. The situation between the public and private sector improved over time, although not all elements of the private sector were involved. Nevertheless, it was difficult to gain full support from the domestic pharmaceutical industry because they preferred lax standards. Civil society was also actively involved in the process. MeTA also supported studies that found high levels of corruption in terms of procurement at the regional level. Key informants noted that there were too many procurement entities that were inefficient and prone to corruption. Members of civil society worked on the monitoring of procurement practices, which was personally risky for some of them. Phase II of MeTA in the Philippines is focused on initiatives such as a feasibility study and needs assessment survey to determine the applicability of an electronic or SMS-based monitoring tool that would allow more efficient collection of price and availability data. This Phase will also pilot the Health Action International assessment tool on medicine promotion, carry out a mapping of drug entitlement programmes, a study on a Transparency Certification Scheme and information and advocacy programmes on medicines quality and entitlements.

The Philippines was also one of the first pilot countries for the Good Governance for Medicines, which worked with existing Government strategies that included improving access to medicines and anti-corruption strategies. The transparency assessment showed that the country was marginally vulnerable in registration, selection procurement (in contradiction to other findings) (Republic of the Philippines Department of Health, n.d.). The key weaknesses included a lack of standard operating procedures and conflict of interest policies. The ethical foundation for Good Governance for Medicines in the country (Phase II) was harmonized with the country's own integrity development program Phase III of Good Governance for Medicines focused on accountability in the system by establishing the Good Governance for Medicines awards and accountability in individuals by developing manuals for registration, selection and procurement which describe corruption risks and how to avoid them (Republic of the Philippines Department of Health, n.d.). Following the Cheaper

Quality Medicine Act of 2008, a National Center for Medicine Access and Management was established (Republic of the Philippines Department of Health, n.d.).

Zambia

MeTA initiated its governance initiatives in Zambia in the aftermath of a corruption scandal. Zambia was the beneficiary of a large number of donor funds for health that includes the pooling of funds through a Sector-Wide Approach, the President's Emergency Plan for AIDS Relief and the Global Fund. In 2009, Zambia's Anti-Corruption Commission discovered that high-level officials in the Ministry of Health had embezzled US$5.7 million. This had been reported to the Anti-Corruption Commission by a whistle blower. A forensic audit of the Auditor General's Office revealed that the funds had been misused through procurement, theft and other breaches. For example, procurement contracts had been awarded to Ministry of Health Officials for amounts that exceeded market prices and many of the goods procured were not delivered. Significant weaknesses in financial management and record keeping were also identified. Following these findings, some donors froze or delayed funding to the health sector.

Initially, the government was reluctant to cooperate with MeTA not wanting external examination of its internal practices, but in time, it did gain its trust. MeTA was also able to bring in civil society and the private sector in an effort to create a meaningful multi-stakeholder alliance. Results related to the pilot project in Zambia include, as noted, the creation of multi-stakeholder alliance on medicines as well as outreach programmes to rural districts and television programmes to raise public awareness about pharmaceutical issues. Moreover, MeTA engaged in policy dialogue with the government on priority issues in the pharmaceutical system, such as improving procurement and regulatory standards and practices.

Zambia is also part of the Good Governance for Medicines Programme and has published its transparency assessment report in 2012. The Report found that the need for more transparency on selection criteria and terms of reference for committee members on medicine committees as well as implementation of drug promotion policies (Handema et al., 2012). Unethical practices were found throughout the system (i.e. bribery of inspectors), even with the marginal vulnerability scoring. It also recommended that the Ministry of Health develop a monitoring and evaluation framework (Handema et al., 2012).

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INDEXING TERMS:
Anti-corruption
Corruption
Health sector
Medicines
Pharmaceuticals

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Corruption in the pharmaceutical system results in wasted resources, limited access to health services and reduced health gains. In this U4 Issue paper, we examine select global initiatives in the area of good governance and medicines that have been applied since the year 2000. These initiatives taken by the World Bank, the WHO and the Global Fund, as well as the Medicines Transparency Alliance, have been particularly useful in generating a political and policy dialogue around the issue of pharmaceutical system good governance. The main findings include that these initiatives identify weaknesses in the pharmaceutical system and can provide important baseline data. They have had the most value in generating a greater awareness about the issue, and in some instances they have also created important multi-stakeholder alliances and implemented sector-specific governance initiatives. However, there is often a significant gap between the identification of problems, the strategic design to address problems and their implementation. The tools used are often focused on the rules, procedures and practices that are assumed to prevent corrupt practices in the public sector, but they may not capture sufficiently well the complex dynamics that lead to corruption. Recommendations include the need for political analysis, and monitoring and evaluation – particularly with regard to the measurement of results – and the streamlining and uniformity of assessment tools across institutions.

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