Tackling Corruption in the Pharmaceutical Systems Worldwide with Courage and Conviction

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Poor drug access continues to be one of the main global health problems. Global inequalities in access to pharmaceuticals are caused by a number of variables including poverty, high drug prices, poor health infrastructure, and fraud and corruption — the latter being the subject of this article. There is growing recognition among policy makers that corruption in the pharmaceutical system can waste valuable resources allocated to pharmaceutical products and services. This, in turn, denies those most in need from life-saving or life-enhancing medicines. As a result, international organizations, including the World Health Organization and the World Bank are beginning to address the issue of corruption in the health sector broadly and the pharmaceutical system specifically. This is encouraging news for improving drug access for the global poor who are most harmed by corruption as they tend to purchase less expensive drugs from unqualified or illegal drug sellers selling counterfeit or sub-standard drugs. In our paper, we illuminate what are the core issues that relate to corruption in the pharmaceutical sector. We argue that corruption in the pharmaceutical system can be detrimental to a country's ability to improve the health of its population. Moreover, unless policy makers deal with the issue of corruption, funding allocated to the pharmaceutical system to treat health conditions may simply be wasted and the inequality between rich and poor in access to health and pharmaceutical products will be aggravated.

Poor drug access continues to be one of the main global health problems.[1] Approximately two billion people or one-third of the global population lack regular access to medicines.[2] The World Health Organization (WHO) estimates that by improving access to existing essential medicines (and vaccines), about 10 million lives per year could be saved.[3] In low- and middle-income countries, more than 70% of all pharmaceutical purchases are paid for out of pocket[4] and often represent the largest household health expenditure.[5] Global inequalities in access to pharmaceuticals are caused by a number of variables including poverty, high drug prices, poor health infrastructure, and fraud and corruption—the latter being the subject of this article. There is growing recognition among policy-makers that corruption in the pharmaceutical system can waste valuable resources allocated to pharmaceutical products and services. This only further denies those most in need of life-saving or life-enhancing medicines. As a result, international organizations, including the WHO and the World Bank, are beginning to address the issue of corruption broadly in the health sector and specifically in the pharmaceutical system. This is encouraging news for improving drug access for the global poor who are most vulnerable to the effects of corruption as they tend to purchase less expensive drugs from unqualified or illegal drug sellers selling counterfeit or substandard drugs.

This paper highlights core corruption issues in the pharmaceutical sector. We argue that corruption in the pharmaceutical system can be detrimental to a country's ability to improve the health of its population. Moreover, unless policy-makers deal with the issue of corruption, funding allocated to the pharmaceutical system to treat health conditions including HIV/AIDS, malaria, and tuberculosis may simply be wasted and the inequality between rich and poor in access to health and pharmaceutical products will be aggravated.

WHY IS THE PHARMACEUTICAL SYSTEM VULNERABLE TO CORRUPTION?

The pharmaceutical system is susceptible to fraud and corruption for a variety of reasons. One reason is that the sale of pharmaceutical products is lucrative, particularly

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because asymmetric information leaves patients more vulnerable to opportunism than customers in many other product markets. Pharmaceutical suppliers (drug manufacturers, importers, wholesalers, prescribers, pharmacists) are profit maximizers. Although this is not inherently bad, if individuals become opportunistic or greedy, they may seek to maximize their interests by going beyond legal and ethical norms. Even in countries such as the United States where strong checks and balances are in place, fraudulent activity in the pharmaceutical sector has been growing; False Claims Act judgments and settlements for fraud have grown to US$12 billion since 1986, most of these cases being against well-known drug companies.[6] In other countries, legal loopholes, a lack of transparency, or oversights by regulators have opened the door for some manufacturers to behave unethically. In the Democratic Republic of Congo, a failure to specify the type of quinine salt associated with the listed dose resulted in one manufacturer selling a sulfate instead of a hydrochloride, which effectively resulted in under-dosing.

Second, the pharmaceutical system in most countries is subject to a significant degree of government involvement, including market authorization, drug selection, procurement, and inspection. Regulatory intervention is often justified in the pharmaceutical sector, given the imperfect nature of the market and the need to ensure drug safety and improve the efficiency of resource allocation. Certainly, without transparency and an accountability framework, regulation in the pharmaceutical sector can be open to capture, deviate from norms, and be vulnerable to corruption. In the transition economies of Eastern Europe, as but one example, the rapid deregulation and privatization of the pharmaceutical sector, combined with an often unstable economic and political environment, not only created opportunities to engage in corruption, but was a survival strategy for many health workers, who were faced with decreasing real incomes and often decreasing relative incomes. In Serbia-Montenegro, the legal batch-testing requirements were used by the domestic manufacturers to impose additional costs on imported competitors. In one case, a noted local manufacturer was reported to have bribed both the Minister and Deputy Minister of Health in order to maintain these discriminatory provisions in a new Pharmaceutical Law introduced in 2003. A study in Uganda found that 68–77% of formal dispensing fees were misappropriated by workers who were also responsible for stealing and reselling publicly procured drugs.[7]

Often, government committees that determine the composition of the public reimbursement lists are susceptible to corruption. The reason is that the inclusion of a drug on such a list can mean significant financial income for a drug manufacturer and relatively predictable market. If this institutional process is not carefully monitored and transparent with solid oversight mechanisms in place, government regulators may be able to make discretionary decisions in the drug selection process where the choice is not necessarily rational. For example, in Trinidad, the government formulary in recent years has included drugs that are questionable selection choices, given the epidemiological profile and budgetary restrictions of the country. In some Balkan countries, dosing was used as a way to secure a formulary listing for a favored local manufacturer where they alone offered a nonstandard dose. In Brazil, 14 were jailed and 25 Ministry of Health employees fired for embezzling US$637 million in the last decade through bribes and price fixing related to reimbursement listings.[8]

To mitigate corruption in the selection process, explicit criteria must be defined ahead of time by an expert committee (whose identity, credentials, and terms of reference for membership on the committee are posted publicly) and published publicly so that stakeholders have a clear knowledge about what criteria are being applied in the drug selection process. Selection criteria should be based on, at a minimum, international standards as established by the WHO and where possible go further. These would include relevance to the pattern of prevalent diseases in a country, proven efficacy and safety according to sound data, evidence of performance in a number of different environments, good-quality drugs, favorable cost–benefit ratio (based on assessment of total treatment cost), preference for drugs that are well-known with good pharmacokinetic properties, and public scrutiny including regular reporting by the media of drug selection meetings.[9] These measures would contribute to increasing transparency and limiting unethical practices.

Equally important, the deletion of a drug from the national drug formulary should be based on sound evidence that the drug is inappropriate or not cost-effective for the health needs of the population. A 2005 United States Agency for International Development study of the Bulgarian National Drug Formulary found under-inclusion of older cost-effective drugs and over-inclusion of compounds of questionable efficacy.[10] Open and formal consultations with the public should be institutionalized to ensure that all the stakeholder views are taken into account in the drug-selection process and in its aftermath and that no one group has undue influence.

Third, it can be difficult to distinguish authentic pharmaceutical products from counterfeit or substandard ones. In many countries with weak regulation and enforcement of drug distribution standards, the sale of counterfeit, unregistered, or expired drugs is very common. WHO estimates that about 25% of drugs consumed in poor countries are counterfeit or substandard.[11] Counterfeiters are often very skilled at copying the form, color, trademarks, and packaging of legitimate products. Although in many markets, patients tend to have more confidence in recognized Western-produced drugs, the high prices for the legitimate versions of these relative to purchasing power drives many consumers to seek low-cost alternatives, which in many cases are not legal, safe, or reliable. Thus, when drug prices are out of reach, they can have significant social costs in terms of access to drugs, particularly for the poor, and they may encourage the growth of a parallel and illegitimate drug supply. Often, it is only when there is blatant sloppiness in copying or unfortunate cases of illness and death, that

Table 1 Core decision points in the pharmaceutical system and anticorruption strategies

Decision point	Selected strategies
Manufacturing	Ensure legal basis for GMP requirement including appropriate and credible fines for noncompliance
	Improve GMP compliance by regular and random inspections
	Hire a sufficient number of trained and well-paid inspectors
	Develop a rotating schedule for inspectors of manufacturing sites
	Publicly post a list of compliant manufacturers
	Publicly "name and shame" noncompliant manufacturers
Registration	Develop transparent, effective, and uniform law and standards for drug registration
	Ensure adequate drug quality control capacity
	Educate the public and professionals to identify unregistered drugs
	Publish drug registration information on the Internet
	Implement market surveillance and random batch testing
Selection	Define and publish clear criteria for selection and pricing
	Drug selection committee membership should be publicly available
	Drug selection criteria should be based on international standards as established by WHO
	Regular reporting by the media of drug selection meetings
	Public posting of results obtained/decisions made
Procurement	Procurement procedures must be transparent, following formal published written procedures throughout the process and using explicit criteria to award contracts
	Supplier selection justified and monitored
	Strict adherence to announced closing dates
	Written records should be kept for all bids received
	Results of adjudication should be made available to all participating bidders and the public
	Regular reporting on key procurement performance indicators
Distribution	Where possible, develop information systems to ensure drugs are allocated, transported, and stored appropriately
	Regular communication between every level of the system to control inventory movements and deliveries
	Appropriately secured storage facilities and transport
	Electronic monitoring of stock in distribution and careful checking of delivery orders against inventories of products delivered to identify theft
Pharmaceutical prescribing and dispensing	Develop and engage professional associations to improve adherence to professional codes of conduct
	Use information systems to monitor physician prescription patterns
	Impose serious penalties and "name and shame" for breaches of legal and ethical standards
	Regulate industry interaction with prescribers through explicit criteria that limit industry gifts and payments
	Require physicians to post industry gifts more than $25 (Vermont Model)[a]
	License and inspect pharmacies

[a]As of 1 January 2004, the State of Vermont requires the pharmaceutical industry to report recipients of gifts more than $25. Some exceptions apply.

patients, health-care providers, and regulatory agencies are able to identify counterfeit medicines. In 1989, 89 people died in Haiti after consuming a paracetamol cough syrup prepared with diethylene glycol, a toxic chemical used in antifreeze.[12] Sub-optimal dosing and rising rates of antimalarial resistance led governments in the Mekong region of Asia to intensify efforts to combat counterfeit drugs.[13]

In both Nigeria and Azerbaijan, involving consumers in the identification of counterfeit medicines has been an important anti-corruption strategy. Consumers are informed about government initiatives and ways to identify potential counterfeit products through various media, including radio, television, and the Internet. A critical part of these initiatives has been the development of a feedback mechanism for

consumers, such as a government-run, toll-free hotline number where they can ask questions or report dubious products or drug sellers.

WHERE IS THE PHARMACEUTICAL SYSTEM VULNERABLE TO CORRUPTION?

The pharmaceutical system is comprised of a number of core decision points along the pharmaceutical value chain, defined as manufacture, registration, selection, procurement, distribution, and prescribing and dispensing (**Table 1**). Each one of these decision points demands uniform and transparent procedures or corruption can take place: the legal basis for drug registration may be weak, vulnerable, or flawed; suppliers may pay government officials to register their drugs without the requisite information; government officials may deliberately delay the registration of a pharmaceutical product to favor market conditions for another supplier; or officials may deliberately slow down registration procedures to solicit payment from a supplier.

Policy-makers need to know the sources of vulnerability to corruption and fraud, and the "best practices" for tackling corruption at each of the decision points along the pharmaceutical value chain. We identify a selection of these decision points in **Table 1**. In this way, decision-makers will be able to identify where and how corruption can or does occur, prioritize areas for intervention, and implement effective anti-corruption strategies to improve transparency and accountability, and protect access to good-quality medicines. There are diagnostic tools now available that can help policy-makers to assess the vulnerabilities of a pharmaceutical system to corruption at these decision points and to prioritize interventions before investments are made to strengthen the system.[14,15] Efforts to mitigate corruption in the pharmaceutical sector depend on decision-makers being familiar with the areas where corruption can occur. This framework and decision tools can be very useful in providing this information.

Decision-makers also need to determine whether areas where anti-corruption strategies that can be implemented easily should be prioritized or whether priority should be given to tackling vulnerable areas with higher returns, although these may involve difficult political negotiations or significant investment costs (*e.g.*, strengthening drug quality control capacity). There is no single prescription; government preferences will vary depending on resources and commitment, and a choice can only be made after a diagnostic of the vulnerability of the pharmaceutical system to corruption is undertaken. Policy-makers must make trade-offs: should we make small gains quickly or try to implement large-scale reform with longer time horizons? Ideally, there should be some combination of the two approaches. Small measures, which demonstrated success in the case of Argentina and Brazil, such as posting pharmaceutical prices hospitals or other institutions have paid for pharmaceuticals on a website, could be undertaken concurrently with larger measures based on international best practices such as investing more resources in a national drug regulatory agency or in enforcement capacity and following international guidelines (such as those prepared by the World Bank) in areas like drug procurement.[16] Together, these will result in pharmaceutical systems that are more robust and less prone to corruption. Success also depends on being able to engage the general public, and where possible the pharmaceutical industry, as participants to ensure the effective implementation of corruption strategies. The International Federation of Pharmaceutical Manufacturers, the association of the research-based pharmaceutical industry, through its affiliate the Pharmaceutical Security Institute (PSI), monitors the sale of counterfeit and substandard drugs including incident reporting, analytical assessments, and dissemination of reports on counterfeiting activities (see www.psi-inc.org).

CONCLUSION

The first step towards stopping corruption in the pharmaceutical sector is to understand its structure, actors, and motivations, and to identify the key points where corruption can occur. Based on this, priority measures to countervail corruption at these points should be identified for the short-, medium-, and long-term. Priorities should be based on the extent to which the identified corruption is a threat to safety and health in the first instance, and secondly, its economic implications irrespective of what priorities are made, transparency and accountability mechanisms are critical at every point in the pharmaceutical system to encourage movement towards stopping corruption sooner rather than later.

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CONFLICT OF INTEREST

Jillian Clare Cohen has worked on corruption issues for the World Bank and the World Health Organization as a consultant and as an employee. Monique Mrazek and Lorraine Hawkins are employees of the World Bank. This perspective is based in part on research we conducted for a forthcoming World Bank publication "Corruption and Pharmaceuticals: Strengthening Good Governance" in "The Many Faces of Corruption: Taming the Elusive Beast". World Bank, Washington, DC.

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