

Efforts are being made to improve the situation. Representatives of the pharmaceutical industry and of physicians describe the voluntary codes set up to reduce potential conflicts of interest. Civil society and concerted efforts by courageous regulators can help curb corruption in the pharmaceutical industries – both legal and counterfeit – as the experiences from India, Thailand and Nigeria show.

## Pharmaceuticals and corruption: a risk assessment

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Pharmaceuticals are indispensable to health systems. They can complement other types of health care services to reduce morbidity and mortality rates and enhance quality of life for many patients. Because pharmaceuticals have curative and therapeutic qualities, they cannot be regarded simply as ordinary commodities. Access to medicines is often about life and death. This is illustrated most dramatically in sub-Saharan Africa where almost 30 million people are infected with HIV/AIDS and the majority lack access to anti-retroviral therapies.

In a broader context, access to essential medicines has become a central topic at the international policy-making level where it is increasingly viewed as a fundamental right, with human rights law placing obligations on states to ensure access.<sup>2</sup> This includes duties on governments to ensure that pharmaceutical systems are institutionally sound and transparent and that there are appropriate mechanisms to reduce the likelihood of corruption, which can deny medicines to those in greatest need.

A major conundrum in international drug policy is the fact that, despite international aid and a plethora of programmes devoted to improving pharmaceutical access, there is a morally worrying ‘drug gap’. The WHO continues to estimate that one-third of the global population lacks regular access to essential medicines.<sup>3</sup> A number of determinants contribute to this drug gap, including market failures, government inefficiencies, poverty and corruption.

For example, OECD countries generally devote US \$239 in annual spending on drugs per head, compared to less than US \$20 in developing countries and US \$6 in sub-Saharan Africa.<sup>4</sup> Pharmaceuticals are the largest public health expenditure after personnel costs in most low-income states, and often the largest household health expenditure of all.<sup>5</sup> One of the most important differences between industrialised and developing countries is that in the latter pharmaceutical expenditures are anywhere from 50–90 per cent of total individual out-of-pocket expenditures.<sup>6</sup> In such countries, illness is a major cause of household poverty. Corruption exacerbates this drug gap: when officials accept kickbacks for purchasing medicines, pharmaceutical expenditure is reduced and fewer of the right drugs get to the right people when they need them.

Many determinants are responsible for disparities in access to medicines, but little research has been devoted to just how corruption impacts on drug availability. Fortunately, this area is gaining interest and a number of studies have begun to address this issue.<sup>7</sup> The pharmaceutical system is susceptible to corruption for a variety of

reasons. One of the most significant is the degree of government involvement in its regulation: studies from other sectors have found that the incidence of corruption is noticeably higher when the state retains a major involvement in the economy and its bureaucracy is pervasive.<sup>8</sup> Without robust institutional checks, government regulators can make discretionary decisions rather than decisions based on uniform criteria. In addition, wide information asymmetries exist between patient and physician (see Chapter 1). Patients trust their doctor to prescribe the most effective drug for their condition, but the doctor's decision as to which drugs to prescribe may be influenced by pressure from pharmaceutical companies. There are often poorly documented processes in the quality control system that can lead to the manufacture of sub-standard drugs. This occurred in Brazil when a well known pharmaceutical manufacturer was found to

### **Box 5.1 US pharmaceutical company fined for payments to charity headed by Polish health official<sup>1</sup>**

In June 2004, the pharmaceutical company Schering-Plough agreed with the Securities and Exchange Commission (SEC) to pay a fine of US \$500,000 for violations of the books and records and internal controls provisions of the Foreign Corrupt Practices Act (FCPA).

According to the SEC's findings, the Polish subsidiary of the New Jersey-based company, Schering-Plough Poland (S-P Poland), made payments amounting to approximately US \$76,000 between February 1999 and March 2002 to a foundation for the restoration of Silesian castles, the Chudow Castle Foundation. The foundation was run by the director of the Silesian Health Fund,<sup>2</sup> one of 16 regional state-run Polish health authorities which provides funding for the purchase of pharmaceutical products by hospitals and other medical centres.

The SEC alleged that these payments were made to induce the director to buy S-P Poland's products for his health fund. It alleged that, in order to conceal the nature of the payments, the S-P Poland manager deliberately set them at or below his approval limit and provided false medical justifications for them in documents submitted to the parent company's finance department.

Although the SEC conceded that the foundation was a bona fide charity and that the donations were made without the knowledge or approval of the US parent company, it charged that the parent's internal controls were inadequate to detect and prevent the financial irregularities committed by its Polish subsidiary. Although the SEC did not go so far as to state that the payments were bribes, it did find that the manager viewed them as necessary, in order to influence the action of the government official.

This case highlights that companies should not only have clear policies covering charitable donations, their permitted amount and approval procedures, but should conduct due diligence across their organisation. The case also underscores the aggressive stance of the SEC in holding suppliers accountable for the actions of their subsidiaries.

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#### **Notes**

1. This text is based on Wilmer Cutler Pickering Hale and Dorr LLP, *Foreign Corrupt Practices Update*, 30 June 2004, [www.wilmerhale.com](http://www.wilmerhale.com)
2. *Rzeczpospolita* (Poland), 11 June 2004.

have manufactured sub-standard contraceptives.<sup>9</sup> Finally, the pharmaceutical market is so lucrative that it attracts entrepreneurs who are both honest and, more perplexingly, dishonest. All of these factors expose the pharmaceutical system to the possibility of corruption.

This essay focuses primarily on the role of government, since state intervention, particularly through regulation, is vital to the pharmaceutical sector. There are two central reasons why governments regulate the pharmaceutical market: first, to ensure that health policy and other governmental interventions, such as quality assurance of drugs and fair drug pricing, enhance the health of the population; and second, to ensure that industrial policies strengthen economic competitiveness of the pharmaceutical sector and improve innovation and efficiency. These two objectives can sometimes lie at cross-purposes. If regulators are subject to pressure from commercial groups, health objectives can be compromised.

### Key decision points

The pharmaceutical system is technically complex and replete with a number of ‘core decision points’.<sup>10</sup> Each decision point needs to function optimally so that the system as a whole offers good-quality, cost-effective, safe and efficacious medicines. Figure 5.1 shows key processes in the selection and delivery of pharmaceutical products and illustrates the potential for corruption that exists at any one of its decision points (post-manufacturing) unless there are solid institutional checks and balances in place. For example, procurement is particularly susceptible to corruption unless there are open bidding processes, good technical specifications, and consistent and transparent

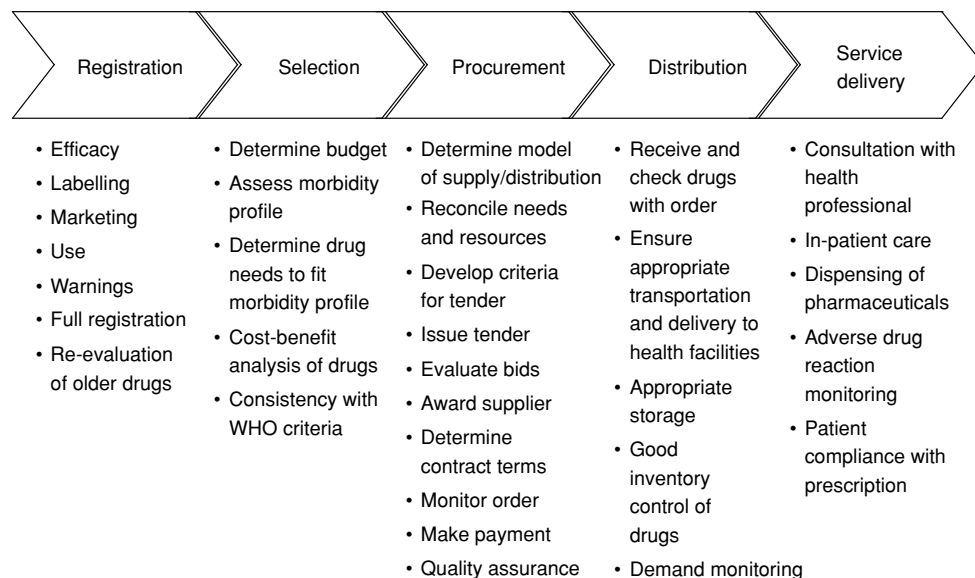


Figure 5.1: Key processes in the selection and delivery of pharmaceutical products

procedures for redress if needed. While the design of good institutions with oversight is crucial for the reduction of corruption, there is also a significant role for civil society. If community groups closely monitor pharmaceutical companies and regulators, there is a greater likelihood that corruption can be caught or even prevented out of fear of disclosure (see Boxes 5.2 and 5.3).

## Registration

The first decision point in the pharmaceutical chain is registration, which was originally introduced to protect patients from catastrophes like the thalidomide cases in the 1950s, and evaluates a drug's efficacy against a specific disease and its possible side-effects. The process regulates the labelling, marketing, usage, warning and prescription requirements for a drug. Registration procedures need to be transparent and applied uniformly, and should leave no room for individual discretion. The registration process should guarantee drug safety and efficacy, but these guarantees risk being eroded by the pharmaceutical industry lobby. A high-profile inquiry into risks posed by the pain pills Vioxx, Bextra and Celebrex in 2004 highlighted already existing concerns regarding the US Food and Drug Administration's (FDA's) capacity as an unbiased regulatory body (see 'The corrupting influence of money in medicine', page 88). Critics point to the fact that between 1997 and 2004, 12 major prescription drugs, with a market value of billions of dollars, were recalled by the FDA or withdrawn by companies. According to Sheldon Krinsky of Tufts University, the rise in for-profit clinical trials, fast-tracking of drug approvals, government-industry partnerships, direct consumer advertising and industry-funded salaries for FDA regulators has contributed to degrading the institutional integrity of the FDA, suggests 'regulatory capture' of the FDA by the pharmaceutical industry to some degree and also illuminates the need for the institution to demonstrate more independence from its stakeholders.<sup>11</sup> Meanwhile, in low-income countries, regulatory agencies are often weak or non-existent due to lack of resources.

## Selection

Drug selection processes should ensure that the most cost-effective and appropriate drugs for a population's health needs are chosen fairly. The WHO Model List of Essential Medicines is a helpful framework in this regard for most developing countries because it establishes priority areas of treatment and covers the most common diseases.<sup>12</sup> But this can open a new avenue for corruption since manufacturers have a strong interest in getting their products selected as essential medicines. If institutions are weak and individuals have incentives to engage in corrupt activities, the selection process can be replete with kickbacks and payoffs so that drugs on a national drug list may not necessarily reflect appropriate and cost-effective drugs (see 'Corruption in hospital administration', Chapter 3, page 51).

However, there are methods that can reduce the likelihood of corruption in the selection process and promote sound, evidence-based decision-making. The pharmacoeconomic techniques used by Australia and the Canadian province of British Columbia

have proved helpful in ensuring that objective decision-making takes place if the correct models and techniques are employed. Pharmaco-economics, or outcomes research, uses cost-benefit, cost-effectiveness and cost-utility analyses to compare the economics of different pharmaceutical products, or to compare drug therapies with other medical treatments.

Drug selection committees must be composed of impartial persons with the appropriate technical skills. Their members must be obliged to declare any conflicts of interest, and meetings should be regular and well publicised so that the public can observe proceedings. Minutes of meetings should be posted on the Internet and decisions clearly justified. In the event of a potential breach, an appeal process must be in place that ensures due process.

Final selection criteria should be based on discussions and acceptance by key prescribers, and the WHO criteria for selection should be used as a basis for decision-making. These are: relevance to the pattern of prevalent diseases; proven efficacy and safety; evidence of performance in a variety of settings; adequate quality, including bio-availability and stability; favourable cost-benefit ratio in terms of total treatment cost; and preferences for drugs that are well known to have good pharmaco-kinetic properties. Lastly, all drugs listed on a government essential medicines list should be identified by generic name.

## Procurement

Procurement is the principal interface between the public system and drug suppliers, and its goal is to acquire the right quantity of drugs in the most cost-effective manner. This involves inventory management, aggregate purchasing, public bidding contests, technical analysis of offers, proper allocation of resources, payments, receipts of drugs purchased and quality control checks.

Procurement is often poorly documented and processed, which makes it an easy target for corruption. Drug procurement is even more vulnerable to corruption than contracting in other sectors. This is due to several factors, including: the method to determine the volume of drugs needed is often subjective; there are difficulties in monitoring quality standards in drug provision; suppliers use different prices for the same pharmaceutical products and can artificially inflate prices; some marketing practices by pharmaceutical companies induce demand for products; and an additional challenge is posed by emergency situations, which call for speedy and adequate intervention.

The best protection against corruption is open, competitive procurement that prevents personal discretion in the selection of suppliers, and requires clear criteria for the selection and process of winning bids. However, procurement procedures require ongoing monitoring, including reviews from the inspector general's office.<sup>13</sup>

Strong oversight mechanisms can drastically reduce corruption. A World Bank study from 2001 examined the use of an electronic bidding system for pharmaceutical purchases in Chile.<sup>14</sup> Contrasting the innovative Chilean system to other procurement practices, the authors argued that outcomes are greatly improved by the adoption of good incentive structures for public officials and the reduction of informational asymmetries through the posting of drug prices on the Internet.

A comprehensive study of corruption in the pharmaceutical system in Costa Rica found that in many cases competition was reduced, or procedures were followed incorrectly.<sup>15</sup> Some health care professionals and pharmaceutical company executives alleged that participants in public tenders had on occasion colluded to extend the purchasing cycle as long as possible. This was done by submitting frivolous appeals, which were then extensively contested by both sides, or by delaying the delivery of drugs for unfounded reasons. The effect of these long delays was the eventual depletion of the social security system's inventory resulting in direct purchases from private suppliers. These purchases were then made at much higher unit prices than would be obtained through formal bidding processes. Studies from Argentina and Bolivia show that increased transparency and citizen participation in the procurement process can reduce corruption and cut costs considerably (see 'Corruption in hospital administration', page 52).

### Distribution

Distribution in the pharmaceutical system ensures drugs are allocated, transported and stored appropriately at all points where they are to be dispensed. This involves central and regional warehouses, pharmacies and service floors. Information must flow easily through every level of the system to control inventory movements and deliveries. In addition, the system requires storage facilities, including refrigeration units, to guarantee the integrity of the drugs and good security to minimise the risk of theft. The electronic monitoring of transport vehicles and careful checking of delivery orders against inventories of products delivered are some of the methods that can reduce this likelihood.

In one Central American country, inventory records showed that stocks of oral antibiotic eye treatment and other products were intentionally oversupplied because government purchasers received commissions for their orders.<sup>16</sup> This demonstrates one way that corruption can drain public expenditure on pharmaceuticals and have the greatest impact on the poor.

### Service delivery

Service delivery involves the participation of physicians, pharmacists, nurses and other health care providers who diagnose patients and identify what drugs a patient should consume to treat a particular disease. This is the decision point at which patients should experience the benefits of the entire system. Here physicians prescribe, pharmacists dispense and nurses administer drugs to treat patients. Health providers ideally utilise evidence-based practice to provide effective therapy to their patients.

The interface between the pharmaceutical industry and physicians is an area that is particularly susceptible to corruption, as service delivery can be influenced by the marketing practices of the pharmaceutical industry (see 'The corrupting influence of money in medicine', page 86).

Some physician–industry interaction is necessary to educate doctors about the therapeutic qualities of new drugs. However, there is compelling evidence that suggests that the motivation is often not health education, but profit maximisation. A 2000

study by Wazana found that physician interaction with the pharmaceutical industry was associated with increased requests for additional drugs on hospital formularies and changes in prescribing practice.<sup>17</sup> The influence of industry on physicians is an issue of concern in both developed and developing countries. But it can be particularly dangerous in developing and transition countries where doctors make paltry salaries and may rely heavily on gifts (both monetary and material) from the pharmaceutical industry to supplement their livelihood.

The US authorities have recently demonstrated concerted efforts to address inappropriate marketing practices by some pharmaceutical companies. In 2001, TAP Pharmaceutical Products was required to pay one of the largest fines in the industry's history, with the government demanding US \$875 million for civil liabilities and criminal charges.<sup>18</sup> Other governments are introducing stricter laws and regulations. For example, in April 2005 a report by the UK's House of Commons Health Select Committee on 'The Influence of the Pharmaceutical Industry' recommended greater transparency in drug regulation processes, reduction in the excessive promotion of medicines, tougher restrictions on physicians to avoid inappropriate prescribing and an end to Department of Health relationships with the drugs industry in favour of the Department of Trade and Industry.<sup>19</sup> Following press accounts of the free trips pharmaceutical companies offer medical doctors and the lavish parties thrown for them, the Deputy Mayor of Social Affairs and Public Health of Helsinki, Paula Kokkonen, banned all trips funded by the pharmaceutical industry for the capital's medical doctors.<sup>20</sup>

In view of the potential for undue influence on prescribing behaviour, global standards have been developed and a number of professional bodies, including pharmaceutical industry associations, have enacted codes of conduct that detail best practice in minimising corruption (see 'Promoting trust and transparency in pharmaceutical companies', page 92, and 'Fighting corruption: the role of the medical profession', page 94). Whether such guidelines have made an impact is questionable. The WHO issued its Ethical Criteria for Medicinal Drug Promotion in 1988, but a 1997 WHO roundtable discussion concluded that inappropriate drug promotion is still a problem in developing and industrialised countries.<sup>21</sup> Even though the criteria have been disseminated widely, their effective implementation is a major problem, as governments need to revise legislation and regulation, and to promote them forcefully in medical schools and associations.

While self-regulatory codes of conduct may be beneficial, they should not delay meaningful reform in terms of external, enforceable regulations. Current voluntary codes are not audited or enforced with meaningful penalties, or overseen by independent and objective observers.<sup>22</sup> More robust policies are needed to address the serious conflicts of interest that arise in the service delivery segment of the pharmaceutical system.

### Counterfeit medicines: the bad and the ugly

When institutions are weak and unable to regulate the pharmaceutical sector accurately, they increase the opportunities for corruption, including the manufacture of counterfeit drugs, a problem that precedes the first decision point in the pharmaceutical chain

in Figure 5.1. For example, regulators may receive kickbacks to ignore makers of counterfeit products, or customs agents may be paid to turn a blind eye to their import or export.

In 2001, China had roughly 500 illegal medicine manufacturers and Laos around 2,100 illegal medicine sellers. In Thailand, sub-standard medicines account for 8.5 per cent of those on the market.<sup>23</sup> India plans to introduce the death penalty for the manufacture or sale of counterfeit medicines that cause grievous harm. 'Profiting from spurious drugs that might harm or kill innocent people is equivalent to mass murder', said Health Minister Sushma Swaraj recently.<sup>24</sup> Meanwhile, an estimated 192,000 people died last year in China because of fake drugs.<sup>25</sup> Regulatory bodies in the South need resources to root out corruption and stem the flow of counterfeit drugs. The success of Nigeria's National Agency for Food and Drug Administration and Control is one example of what can be achieved through strong leadership (see page 96).

### Moving forward: how to do better?

Corruption in any one of the critical decision points in the pharmaceutical system can be harmful to a country's ability to improve the health of its population by limiting access to high-quality medicines and reducing the gains associated with their proper usage. While corruption affects the entire population, it is typically the poor who are most susceptible when officials hoard drugs, or waste resources on the wrong kind of medicines. Good governance is therefore a *sine qua non* for ensuring better access to essential medicines.

Greater transparency in the pharmaceutical system will help to improve drug access. Honest assessment of the institutional robustness at all core decision points in the pharmaceutical system is the first necessity. Governments need to know what areas of the system are less than optimal and vulnerable to corruption. There is a need for more monitoring of how pharmacies, hospitals and health care providers are reimbursed for drugs. Further research is needed to determine what systems offer the best incentives for providers to behave honestly and control fraud. Second, consumer groups and other third parties need to be vigilant about monitoring both the public and private pharmaceutical systems to ensure they are directed towards the public interest.

While international statements and professional guidelines on best practice are well intentioned, they are meaningless unless they are properly enforced. Individual governments must have the courage to enact and, most importantly, to implement policies and processes which encourage ethical behaviour and punish firms and individuals for corrupt actions. If this happens, hopefully we will see a change for the better in terms of ensuring that people in need get the right drugs at the right time.

### Notes

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## The corrupting influence of money in medicine

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Pharmaceutical, device and biotechnology companies have created new drugs and devices that have prolonged the lives and improved the health of millions of people. Many interactions between academic scientists and industry have been responsible for such advances, and these collaborative research projects should be encouraged. Yet the