Following a complaint from VIVAS Health, the European Commission has insisted that VHI’s derogation be removed. Such a change was mooted some time ago, as outlined in a White Paper produced by the then government in 1999, but not acted upon. Legislation to put this into effect is currently being debated in parliament.

Where do we go from here?
While risk equalisation has been given legal backing by the Irish High Court and the European Court of First Instance, the Supreme Court judgment is still awaited, and it remains to be seen whether the Court of First Instance judgment will be appealed to the European Court of Justice. Further legal challenges are also pending in the Irish courts, and Sean Quinn, Chairman of the Quinn Group, has vowed to continue fighting risk equalisation.

The legislation being debated in the Irish parliament aims to oblige VHI to meet the same prudential regulatory standards as its competitors by the end of 2008. It is not yet clear whether this will satisfy the European Commission, which gave the Irish government two months from November 2007 to comply.

It would appear therefore, that whatever the short-term outcomes, it could be some time before these issues, and in particular risk equalisation, are fully resolved.

Governance in the pharmaceutical sector

Armin Fidler and Wezi Msisha

Summary: Pharmaceutical products are an important element of health systems that often make a difference in health outcomes, particularly for the poorest people. Despite this, global inequalities in access to pharmaceuticals persist, due to a number of factors including poor governance and corruption. This article provides a general overview of the pharmaceutical sector’s vulnerability to corruption, reviews initiatives to improve governance in this sector within the Eastern Europe and Central Asia region and concludes by making recommendations for further addressing this issue.

Key words: Governance, Corruption, Pharmaceuticals

Pharmaceuticals are an indispensable ingredient of modern health technology and as such also constitute an important and increasing share of health expenditures globally. In many transition economies in Europe the allocation for pharmaceuticals routinely exceeds a quarter of the annual health budget. For economic and health impact reasons, sound pharmaceutical policies and regulations, minimum quality standards for drugs, transparent licensing, registration and procurement and evidence-based prescription practices are a concern for both consumers and policy makers. Good governance and absence of corrupt practices is important for the performance of health systems in general, and international evidence shows that governance break-downs and corruption in the pharmaceutical sector has serious negative repercussions for the effectiveness of the health system in general.1,2

The importance of governance in public policy and development
The World Bank renewed its commitment to focus on governance and anti-corruption as a key development challenge and has developed a new strategy on good governance.3 Indeed, corruption has been identified by development practitioners as one of the most important obstacles to economic and social development, as it distorts the rule of law and weakens the institutional foundations which are necessary for economic growth. Importantly, the poor are the ones most affected by bad governance and corrupt practices as they often depend on the provision of public services and are least able to afford the costs associated with bribery and fraud.4

For these reasons the World Bank has come up with a new strategy and plan for strengthening its engagement with and support for client countries on these issues. Since the mid-nineties, the World Bank’s world-wide "Governance Indicators Project" has periodically reported on individual and aggregated governance indicators covering six aspects: (i) voice and accountability; (ii) political stability and the absence of violence; (iii) government effectiveness; (iv) regulatory quality; (v) rule of law; and (vi) control of corruption. This exercise covering 212 countries allows assessment of their progress on these governance aspects.5 Good governance in
all sectors has therefore emerged as a crucial aspect of the global development agenda, as it has been shown empirically to affect income levels, economic growth and macroeconomic policies. One of the key areas in the fight against poverty is to invest in human capital, which entails improvements in the social sectors, particularly education, social protection and health.

**Governance is a critical element in the management of health systems**

Global research has shown that wide discretion, lack of transparency in decision making and lack of accountability for decisions made are some of the conditions that create opportunities for corrupt practices and increase the likelihood of governance breakdowns. Good governance within health systems and accountability of service providers are therefore essential for functioning health systems to deliver preventive and curative services to their constituency and hence contribute to improved health outcomes.

According to Transparency International, more than US $3 trillion is spent on health services globally each year. But on average, 10–25% of public procurement spending in the health sector is lost to corruption. Despite increasing awareness of the consequences of poor governance in general, the specific issue of governance in health care has somehow received less global attention thus far. Recent work on corruption in the pharmaceutical system has highlighted the particular importance of governance in the pharmaceutical area as an important element within the health sector and its important contributions to health care and health status in general. As a result, this has become a priority concern of international agencies and foundations.

**Governance and the pharmaceutical system**

Pharmaceuticals are a critical, high value input for health delivery systems that often make a difference in health outcomes for individuals and an entire population. Access to high quality medicines is a non-trivial issue, especially for disadvantaged, poor and vulnerable populations. Despite international aid, the advent of specialised agencies and funds (such as the Global Fund to Fight AIDS, Tuberculosis and Malaria) and many government sponsored or donor programmes devoted to improving global pharmaceutical access, there is still a concerning drug supply gap.

The value of the global pharmaceutical market is estimated at over US$500 billion, making the pharmaceutical sector highly lucrative but also increasingly vulnerable to corruption and unethical practices. Because of their therapeutic and curative qualities, access to quality pharmaceuticals oftentimes means the difference between life and death. Despite this, poor access to drugs remains a major global health problem with close to two billion people or one third of the global population lacking regular access to essential medicines.

According to World Health Organization (WHO) estimates, approximately ten million lives could be saved every year through the improvement in access to essential medicines and vaccines. Several factors contribute to the problem of unequal access to pharmaceutical products and these include market failures, government inefficiencies, costly drug prices, poverty, poor health infrastructure and corruption. Transparency International estimates that globally two thirds of medicine supplies in hospitals are lost through corruption and fraud.

A governance breakdown in the pharmaceutical sector not only generates a negative economic impact but also puts at risk the health gains of patients. A more intangible side effect of inefficiency and lack of transparency and corrupt practices is that it undermines the credibility of public institutions and erodes public and donor confidence in government capacity. Not surprisingly, in the opinion of European citizens in transition economies, the public health system was perceived as the public service institution where corruption occurred most frequently according to results from the recent Life in Transition Survey conducted in Eastern Europe and Central Asia.

The procurement and sale of pharmaceutical products (together with other high technology investments in health) is a lucrative business in most countries, because of the high value of the goods involved and because final consumers are more susceptible to opportunism than niques by physicians for specific drugs, lead to a high rate of prescriptions that are not based on medical evidence, best practice or the patients need. Unscrupulous importers, wholesalers and distributors tend to maximise their profits and exploit unregulated or under-regulated markets. Similarly, corruption and taking advantage of weak regulatory and enforcement capacity underpins the lucrative counterfeit drugs trade.

Payoffs at every step of the supply chain allow the flow of counterfeit drugs from their source to consumers in many transition economies, with a particular problem arising in Central Asian countries. With pharmaceuticals often being the largest household health expenditure in developing countries, (often more than 50% of total individual out of pocket health expenses) corruption in the pharmaceutical industry has a direct impact on low income patients.

Finally, the complex processes and the many steps involved in the pharmaceutical supply chain in order for drugs to get from production to market to the final consumer also increase the chance that fraudulent activity will thrive, as the
example of the sale of counterfeit or low quality drugs to patients in many countries demonstrates. WHO estimates that up to 25% of drugs consumed in developing countries are counterfeit or sub-standard. Furthermore, corruption in this sector can eventually have a negative effect on national health budgets. Poor governance in the pharmaceutical sector results in the waste of scarce public resources which reduces the ability of governments to provide access to high quality essential medicines and this in turn increases the potential for unsafe medical products to enter the market.

For example, an assessment of governance in Bulgaria’s pharmaceutical system found that the selection and procurement of pharmaceuticals was insufficiently transparent and too vulnerable to conflicts of interest. There was little effective oversight in the drug selection process and very limited public input. The study also found evidence of attempts by some international and local drug producers to exert influence at almost every level of the system.

In many transition economies, in particular in South Eastern Europe, the rapid deregulation and decentralisation in the pharmaceutical sector, combined with unstable economic and political environments created governance vulnerabilities in the health sector. In particular the procurement practices were vulnerable to undue influence during drug selection, kickbacks or bribes that enabled bidders’ to access confidential information and use of direct procurement instead of competitive bidding.

Albania and Macedonia are among the countries in the region that have made significant strides to introduce a more transparent public procurement and international tendering system. Azerbaijan advanced in modernising the central drug laboratory and retrained critical technical staff. Furthermore the country succeeded in implementing regular batch testing of drugs, introducing tamper proof packaging and establishing a hotline for consumers and drastically increased the seizure of unregistered drugs on the market.

Good governance is key to ensuring a sound and well functioning pharmaceutical system that provides good access to essential medicines for the population of any country. Governments are obliged to establish and maintain sound institutional structures and policies in order to ensure the wellbeing of their citizens. Governmental responsibility in the pharmaceutical sector is two-fold; first, it involves regulation of the manufacturing, distribution, sale and use of pharmaceutical products. Second, it relates to selecting, purchasing, and logistically managing drugs for use in public health care systems in those situations where governments are the primary providers of drugs to the public.

Government involvement, especially through regulation of pharmaceutical policies on procurement, quality control, pricing and prescribing, is crucial in order to maintain an efficient pharmaceutical sector. Tools such as Health Technology Assessments and other means of sharing international evidence and best practice are helpful in attaining this goal. Governmental regulation of the pharmaceutical industry must balance the concern for the health of the population on one hand with the promotion of industrial and trade policies to strengthen competitiveness, foster innovation and promote cost-effectiveness on the other hand.

### Soft spots in the pharmaceutical supply chain
The pharmaceutical supply chain is different from other commodities in the

### Box 1. Decision points and selected strategies

<table>
<thead>
<tr>
<th>Category</th>
<th>Strategy</th>
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<tr>
<td><strong>Manufacturing</strong></td>
<td>Establish and secure legal framework for Good Manufacturing Practice (GMP) for local manufacturers in respective country and introduce appropriate fines for industry for non-compliance with legal stipulations and quality standards and post publicity a list of compliant manufacturers.</td>
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<td>Retain a sufficient number of trained and well-paid inspectors and on a rotating schedule carry out regular random inspections to assure GMP compliance.</td>
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<tr>
<td><strong>Registration</strong></td>
<td>Establish transparent, effective and uniform laws and standards for drug registration to assure adequate drug quality control capacity.</td>
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<td></td>
<td>Publish drug registration information on the Internet and educate the public and professionals to identify unregistered drugs.</td>
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<td></td>
<td>Implement market surveillance and random batch testing.</td>
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<tr>
<td><strong>Selection</strong></td>
<td>Define and publish clear criteria for selection and pricing based on international standards as established by the WHO.</td>
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<td></td>
<td>Publish drug selection committee membership and meetings schedule and results obtained/decisions made.</td>
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<tr>
<td><strong>Procurement</strong></td>
<td>Assure transparent procurement procedures, written procedures and explicit criteria for contract awards with strict adherence to announced closing dates.</td>
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<td>Monitor supplier selection and keep written records for all bids received; make adjudication available to all participating bidders and the public.</td>
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<td>Report regularly on key procurement performance indicators.</td>
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<td><strong>Distribution</strong></td>
<td>Develop information systems to ensure drugs are allocated, transported, and stored appropriately.</td>
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<td></td>
<td>Assure regular communication between every level of the system to control inventory and deliveries.</td>
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<td></td>
<td>Secure appropriate storage facilities and transport.</td>
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<td></td>
<td>Establish electronic monitoring of stock in distribution and check delivery orders against inventories of products delivered to identify theft.</td>
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<td></td>
<td>Develop and engage professional associations to improve adherence to professional codes of conduct.</td>
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<tr>
<td><strong>Pharmaceutical prescribing and dispensing</strong></td>
<td>Use information systems to monitor physician prescription patterns.</td>
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<tr>
<td></td>
<td>Impose penalties for breaches of legal and ethical standards.</td>
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<tr>
<td></td>
<td>Regulate industry interaction with prescribers through explicit criteria that limit industry gifts and payments and require physicians to post industry gifts.</td>
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<tr>
<td></td>
<td>License and inspect pharmacies.</td>
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Source: Adapted from. Framework originally developed by USAID.
market as it is highly complex, technically challenging and fraught with market failures due to information asymmetry and hence more vulnerable to governance breakdowns and corruptions at every link in the chain. Based on a framework originally established by USAID, and further adapted by Cohen et al, the drug supply chain can be broken down into manufacturing, registration, selection for reimbursement, procurement, warehousing and distribution and prescription/service delivery. Box 1 demonstrates key decision points and required minimum policies at every link in the chain.

The potential for mismanagement and corruption exists at all these decision points unless there are strong institutional checks and balances maintained and oversight mechanisms in place to prevent abuse. In many transition economies government officials often have a (near) monopoly on a number of these decision points, which increase the system’s susceptibility to mismanagement, fraud and corruption. For instance, government officials are involved in determining the selection of drugs for inclusion in national formularies, a process which can be marred by corrupt practices, since it is in the interest of manufacturers (and often a significant economic windfall) to have their products included on essential drug lists. Weak institutional processes therefore can result in national formularies including drugs that are not necessary or the most cost-effective.

**Governance initiatives and assessment tools in the pharmaceutical sector**

Given the negative consequences that corruption in the health sector, and in the pharmaceutical area in particular, can have on the lives of people, there is a strong case for government regulation of this market. Based on international evidence it is essential for governments to exercise strong leadership and establish a framework for the rule of law and good governance practices as a key element to regulate the health and pharmaceutical sector. An important first step is the identification of market failures and the causes and motivation underlying corrupt practices, the people involved, as well as the areas most susceptible to corruption. Measuring, documenting and communicating instances of abuse, corruption and mismanagement is critical, as this can highlight areas where interventions can be made.

Useful policy tools have been developed to attempt to assess weak links within pharmaceutical systems. One of these is the Pharmaceutical Assessment Tool, first developed by Cohen et al and further enhanced and adapted by the WHO which builds on early work done by Klitgaard. According to Klitgaard’s schematic equation, corruption \( C \) equals monopoly \( M \) plus discretion \( D \) minus accountability \( A \), resulting in:

\[
C = M + D - A
\]

This equation identifies key conditions that facilitate corruption in a system, including in a country’s pharmaceutical system. The WHO assessment tool utilises standardised questionnaires to assess vulnerability at key decision points in the pharmaceutical system. A ten point rating system which ranges from ‘extremely vulnerable’ to ‘minimally vulnerable’ is used to assess a system’s degree of vulnerability to corruption. This was first tested successfully in Costa Rica and has since been used in a number of countries, including in some transition countries in Europe, such as in Albania (Box 2).

Since 2004, the World Health Organization (WHO) has undertaken the Good Governance for Medicines Program the goal of which is to reduce corruption in pharmaceutical systems “through the application of transparent, accountable administrative procedures and the promotion of ethical practices among health professionals”.

A three step approach has been identified in implementing this initiative and it includes:

(i) a national assessment of transparency and vulnerability to corruption, which involves the use of a standardised assessment instrument that builds on the tool described above;

(ii) the development of a national programme on good governance for medicines; and

(iii) implementation of the programme (see Box 2).

The programme is currently operational in ten countries and is expected to further expand to other countries based on requests from concerned governments. Related to this, the WHO has also developed The Manual for Measuring Transparency to Improve Good Governance in the Public Pharmaceutical Sector, which details fifty-one indicators that can be collected to monitor transparency under the areas of registration, promotion, inspection, selection, and procurement. In addition to this, the World Bank has through projects and technical assistance worked with countries to identify and address policy issues in their pharmaceutical sectors as well as improve their pharmaceutical procurement systems among other things.

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* Robert Klitgaard did seminal work that defined corruption and its characteristics.
Conclusion
Pharmaceuticals are a key input into health care and cover a large, and for many countries a growing share of the health budget. They are a high tech, high value input to achieve and maintain health outcomes for a population. In its extreme, access to drugs can mean the difference between life and death in many circumstances, especially for the poor and vulnerable populations. As in the health sector in general, pharmaceuticals are no exception to the issue of market failures due to information asymmetry. As such, this sector requires strong and effective regulation and governance practices in order to avoid mismanagement and opportunities for corruption and to ultimately minimise the occurrence of adverse outcomes for the consumers of drug products.

Europe's transition countries and developing countries in general often lack a sufficient legal and regulatory framework in the health sector and are often times in just the process of establishing the rule of law in public policy. Similarly, professional associations have only begun to establish codes of conduct and standards for their members and are only starting to attempt to enforce self regulation for transgressors among their membership.

In order to achieve a coherent evidence and rules based system for pharmaceutical governance, it has been shown to be important to ensure intergovernmental collaboration, (health, law enforcement, customs, judiciary, etc). Additionally, the consumer increasingly also has an important role to play. As consumers are getting better informed, they will demand greater transparency in pharmaceutical systems and from their service providers. Evidence has shown that increasing consumer awareness can result in achieving support for particular challenges such as the control of counterfeit drugs etc.

Governments, in addition to establishing the legal and regulatory framework described above should also get involved in monitoring their pharmaceutical systems performance through international benchmarking and promote accountability of the respective stakeholders involved. Finally, professional organisations, particularly in transition countries, should be supported but also be held accountable for implementation of policies and professional guidelines that promote ethical behaviour of their members.

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Available at: http://www.who.int/medicinedocs/fr/d/Jwhozip27e?