

# Assessment of Governance and Corruption in the Pharmaceutical Sector

Lessons Learned from Low and Middle Income Countries

Aissatou Diack, Andreas Seiter, Loraine Hawkins and Imad Subhi Dweik

January 2010





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## Health, Nutrition and Population (HNP) Discussion Paper

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**Abstract:** Pharmaceuticals are a critical input for the health sector. At the same time, the drug business sustains many individual and corporate livelihoods and produces handsome returns for those involved in the trade. Good governance is critical for the sector to maximize returns for public health and minimize risks for patients from ineffective or contaminated drugs. Given the large financial volume of the market, the potential for corruption is significant. Vulnerable points are those at which decisions about market access and purchasing are made. This includes institutional functions such as licensing, inclusion into formularies and public procurement as well as the individual prescriber, who selects drugs for a specific patient. Given the political and institutional resistance against more transparency from the beneficiaries of the status quo, assessment of governance and corruption in the sector is not a straightforward exercise. We developed a more indirect approach that relies on a broader assessment of the functioning of the sector and detection of patterns that suggest governance or management problems. From a developmental perspective, the focus is on reducing the impact of bad governance (high drug prices, stock-outs, bad quality of drugs in circulation, irrational use of drugs) rather than identifying the actors and bringing them to justice. Even if the governance level cannot be touched due to political resistance, it may be possible to address the problem from a technical or management angle. For example, electronic procurement platforms and inventory management systems make manipulation more difficult and allow for a faster discovery of irregularities.

The assessment framework was applied in eight countries, with adjustments based on client demand and political viability. In most cases, a follow-up after the assessment could be documented, showing that the data provided had relevance and impact in the national policy dialogue. Three of the eight countries signed up to a longer term program to increase transparency in the sector (Medicines Transparency Alliance), others initiated specific projects to address issues that were presented as a result of the initial assessment. In summary, our work could demonstrate that it is possible to effectively address pharmaceutical governance issues in the context of a broader sector assessment – an approach that may face less political resistance than an inquiry based on a “governance and corruption” labeled instrument.

**Keywords:** pharmaceutical sector assessment, governance, corruption, market failure

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## **Glossary of Terms**

ACT	Artemisinin Combination Therapy against malaria
COP	Community Outreach Pharmacy program (Liberia)
DPD	Department of Pharmacy and Drugs (Benin)
EU	European Union
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HIF	Health Insurance Fund
IMS	Company that provides pharmaceutical market data in developed and middle income markets
INN	International Non-proprietary Name
LIC	Low-income country
LMIC	Lower-middle-income country
MDGs	Millennium Development Goals
MeTA	Medicines Transparency Alliance
MOH	Ministry of Health
MSH	Management Sciences for Health
NDS	National Drug Service (Liberia)
NGO	Non-governmental organization
NHIA	National health Insurance Authority (Ghana)
OEBIG	Austrian Health Institute
OECD	Organization of Economic Collaboration and Development
OTC	Over the Counter
PER	Public Expenditure Review
PT ASKES	Public sector health insurance fund (Indonesia)
QA	Quality Assurance
R&D	Research and Development
Rx	Prescription drugs
TRIPS	Trade Related Aspects of Intellectual Property Rights
VAT	Value Added Tax
WHO	World Health Organizatio

## **Introduction: Pharmaceutical Governance Issues are Relevant for Development Outcomes**

Pharmaceuticals are a critical input into health service delivery for all of the health-related millennium development goals (MDGs) as they make a clear difference in health outcomes of individuals. WHO estimates that ten million lives could be saved every year through the improvement in access to essential medicines and vaccines<sup>1</sup>. In countries experiencing an epidemiologic transition, where communicable and non communicable diseases coexist, access to affordable drugs is increasingly important for the prevention and treatment of the growing burden of diabetes, cardiovascular and cerebrovascular diseases and cancers. Several factors explain why out-of-pocket spending on pharmaceuticals is a large, often dominant, component of private health expenditure in most low-income countries (LICs) and many lower-middle-income countries (LMICs). Public facilities have poor availability of essential drugs, despite all donor or government sponsored programs devoted to improving access to pharmaceuticals. In addition, medicine prices are often high in the formal private sector where off-patent multi-source medicines are sometimes more expensive in middle-income countries than in high-income countries. In some countries, there is also a large informal private sector selling products of dubious quality, without any competent advice on appropriate use. Emerging social and community health insurance schemes in LICs and LMICs often provide limited or no coverage for outpatient prescription drugs.

Poor policies, weak institutional capacity for policy implementation and enforcement of regulation, and failure of public sector governance systems underlie many of the problems observed in pharmaceutical sector governance. First of all, public sector function related to the regulation, financing, procurement and logistics for pharmaceuticals are technically and managerially demanding. Secondly, government decision-making and intervention in the pharmaceuticals sector is vulnerable to state capture by global or local pharmaceutical industry interests and other organizations involved in the supply chain. In addition, outright corruption in procurement has been identified in development projects and government programs. Payment of bribes to regulators or use of political connections also undermines enforcement of regulation in countries where rule of law is weak. Diversion, theft and wasteful mismanagement are observed in public sector pharmaceutical supply chains. In countries with health insurance coverage, reimbursement systems for drug expenditure are prone to fraud or abuse. Finally, in countries where health facilities have inadequate public funding for supplies, or where health care workers are poorly paid and seldom supervised, it is common for health workers to sell drugs for a profit, or accept unethical financial incentives from drug suppliers in order to supplement their income. This puts them in a position of conflict of interest in advising patients on health care, and leads to excessive and inappropriate prescribing.

In attempting to assess the pharmaceuticals sub-sector, it is often difficult to tell whether observed problems in the sector are due to unclear or sub-optimal policies, inefficient and incompetent management, or conscious violation of rules for personal gain. Often, all of these elements appear to be present together, and exacerbate each other in ways that entrench patterns of dysfunction.

## **Assessment Methodology, Policy Relevance and Impact Measurement**

WHO offers a standardized instrument for assessing “vulnerability to corruption” at each of several critical decision points in pharmaceuticals regulation, procurement and supply chain management<sup>2</sup>, developed by Cohen, Cercone and Macaya and first applied in Costa Rica in 2002. Applying such an instrument requires high level commitment from the client side and openness to talk about corruption, which may lead to a self-selection of countries that have less governance problems from the outset. The WHO instrument is fairly broad in terms of areas covered and requires structured interviews with many different stakeholders, which makes it an interesting tool from an academic perspective (potential cross-country comparability of results, comprehensive assessment of the entire sector) but limits its utility in cases in which the time window and resources for an assessment are limited. Another potential issue with the WHO instrument is the verification of answers given by different stakeholders to interviewers, who may have been trained with the instrument but not necessarily have a lot of experience in the sector.

The realities of the World Bank’s health sector engagement in specific countries, which is based on results-focused partnership agreements with client governments, requires a more contextual approach with high flexibility in terms of the specific focus. Usually, client representatives and Bank staff have an idea which part of the sector is potentially affected by governance problems. Political sensitivities on the client side may define which aspects of governance and management could realistically be addressed through reform efforts and which ones are “too hot to touch”. Other criteria guiding the assessment focus could be potential synergies with the ongoing work of Bank health teams and/or other development partners.

As pointed out above, symptoms of dysfunction in a health system, such as for example stock-outs of essential drugs, high prices in certain market segments or inadequate prescribing practices, can have their origin in simple financing and capacity problems as well as in problems related to governance and corruption. Hence an assessment tool used to inform policy decisions should be neutral in its diagnostic approach and not pre-empt conclusions by limiting the scope of questions to only one potential causality. Such a tool needs to verify, describe and as much as possible quantify the problem. The data generated by the assessment then provide a basis for the analysis of potential causalities. The analytical process is one that requires expert knowledge in interpreting data and dialogue with insightful stakeholders to reach useful conclusions. In many cases, data will be incomplete and opinions between stakeholders diverging, so that aspects of political acceptance, experiences from other countries and the general “do no harm” principle will guide the final recommendations. Fortunately, measures to improve management for example in the drug supply chain also have a positive effect on governance, as they improve availability of data and transparency of transactions and thereby increase accountability of decision makers.

Another advantage of a neutral assessment tool is that it is easier accepted by stakeholders than a tool that is designed explicitly to assess corruption risk, in particular in countries that may have significant governance problems.

A neutral assessment tool can be used as a stand-alone or as part of an overall analysis of country health systems performed by the Bank in partnership with the governments and other development partners. The tool that was used is basically a structured checklist covering the relevant aspects of the pharmaceutical sector, defining which data need to be collected and offering potential data sources at international level and within countries (see Annex 1). The main areas covered are

- Pharmaceutical market
- Pharmaceutical policy and regulation
- Public and private drug expenditure
- Drug pricing
- Purchasing, procurement and reimbursement
- Service delivery and logistics
- Industry and trade
- Rational use of drugs

This generic tool then needs to be customized by the expert doing the assessment to match the situation in a given country and the requested scope of the work.

Data and information collected from available sources is then reviewed and assessed against the background of the expert's individual framework of knowledge and experience in similar situations. This part of the analytical process can best be described as a "pattern recognition" process that leads to an initial hypothesis on the causes for the identified problems.

If an assessment is done for the purpose of catalyzing change in a dynamic policy environment, it may be necessary to simplify messages and tweak them in a way that resonates with perceptions of policy makers and key stakeholders. Finding the right balance between being truthful and comprehensive in presenting results of an analysis and being diplomatic enough to achieve optimal political traction is part of the "soft skills" characterizing effective development work. To this extent, the policy dialogue with client representatives that follows the initial analysis and leads to an assessment report with conclusions and recommendations is a translational process influenced by the facts uncovered during the assessment, the personal reference framework of the expert and the political reality on the client side. Comparability between countries or adherence to standards of academic excellence are secondary considerations that may need to be compromised (within limits set by honesty and credibility) if they would otherwise undermine the effectiveness of the work in triggering policy changes.

As an analogy to illustrate this potential conflict, one could imagine a patient visiting a doctor complaining about stomach ache. After talking to the patient and doing the usual tests, the doctor diagnoses a duodenal ulcer and concludes that the patient's bad lifestyle choices (heavy drinking, smoking, unhealthy diet) in combination with stress on the job are the likely cause. However, the patient is in denial and not willing to engage in a discussion on life style (maybe because he has stress on the job right now), so the doctor just prescribes a drug that cures the ulcer. While this is theoretically a sub-optimal intervention, in the given situation it is the preferred choice because it preserves the relationship with the patient. Once relieved of the pain, the patient may be accessible at a later time for a discussion about more fundamental changes to his life style. Forcing this discussion on him while he is in denial would just make him leave and seek care at another place.

Similarly, in practical development work, a certain degree of opportunism and adjustment to client expectations is needed sometimes to maintain constructive relationships, which in the longer term may create opportunities for more fundamental changes. As an example, the assessment of the pharmaceutical sector in a low-income country may suggest that drug availability in public clinics is low, despite significant inflows of funds at the central level, where procurement takes place. Anecdotal reports of drugs purchased for the public sector being seen in private drug seller's shops and mobile carts, combined with unwillingness or inability of the central procurement unit and central medical store to provide meaningful data about purchasing and throughput of drugs complete a diagnostic pattern that suggests that there is significant "leakage" in the public system. However, the counterpart in the ministry of health may not be empowered to make changes or otherwise challenge the procurement unit. An alternative problem solving strategy in such a case could be to allow providers to purchase from the private sector if the public sector supply chain fails them. While this does nothing to immediately address the likely governance problems in the public sector supply chain, it will (1) benefit patients and outcomes, (2) change the market dynamics and, if it leads to higher drug availability in facilities, (3) affect the power balance to the disadvantage of those who currently appear to undermine the system.

For the work reported here, the country selection was based on demand, triggered by World Bank task team leaders or clients describing a need to assess the pharmaceutical sector and implement reforms to improve health system performance. Specific entry points are provided in Annex 2, which summarizes the individual country reports. Countries participating in the analysis represent four Bank regions:

- Peru (Latin America and the Caribbean)
- Indonesia and Timor Leste (East Asia and Pacific)
- Benin, Ghana and Liberia (Africa)
- Yemen and West Bank Gaza (Middle East and North Africa).

*Table 1: overview of the pharmaceutical sector in the eight countries that participated in the assessment*

Country	Drug expenditure per capita in US\$	% Private expenditure for drugs	Centralized regulatory agency	National quality control lab	Public sector supply chain
<b>Benin</b>	15 (estimate)	95%	Yes	Yes	Yes
<b>Ghana</b>	15 (estimate)	30%	Yes	Yes	Yes
<b>Indonesia</b>	12	high	Yes	Yes	Yes
<b>Liberia</b>	No data	high	No	No	Yes
<b>Peru</b>	35	75%	Yes, but weak law allows unregulated drugs on market	Yes	Yes
<b>Timor Leste</b>	No data	No data	In development	No	Yes
<b>West Bank/Gaza</b>	35-40 (estimate)	75%	In development	Yes (contracted)	Yes
<b>Yemen</b>	9	>90%	Fragmented	No	Partial

All the countries that agreed to participate in the assessments preferred to look into governance and management issues more broadly, rather than focus on corruption. This approach provides a softer entry point, avoids the perception that the assessment is a forensic audit, and is consistent with recognition that corruption is only one of a range of possible results of poor governance. It also recognizes, as pointed out above, that the policy and institutional environment in which corruption occurs needs to be understood, in order to set realistic priorities for action.

Some of the participating countries (Benin, Peru, West Bank Gaza, Yemen, and Timor Leste) requested a comprehensive assessment of all the main functions related to the pharmaceutical sector, as a basis for identifying a future agenda for change. Other countries preferred a partial sector assessment of priority areas of concern (for example the need to control national health insurance spending on pharmaceuticals benefits in Ghana). Additionally, some of the participating countries (Indonesia, Benin) had already implemented the transparency assessment with WHO support, and were looking for complementary assessment of the causes of persistent problems, and/or advice on actions to address the problems.

Given the nature of the work, there is no simple framework for assessing the impact of a diagnostic process that leads to a set of conclusions and recommendations, at least not within the short timeframe available for observations between the country assessments and the drafting of this paper. Proxy markers that are easily observable and signal at least the possibility for positive change are

- Requests for follow-up work by the government
- Institution of working groups or other actions implemented by the government after the work had been delivered
- Participation in other, bilateral or multilateral partnerships or projects that point in the direction suggested by the analysis

## **Results Overview**

***Dominant role of private sector:*** In all countries assessed, most pharmaceuticals are purchased from the private sector and financed out of patients' pockets. Private sector prices of originator brands, even those for which there are multiple branded and unbranded generics available, are a high multiple of the median reference price reported by Management Sciences for Health (MSH). The median reference price is derived from international competitive procurement. There also is a wide range of prices for generic forms of the same medicine: some "premium" branded generics are sold at similar prices to originator products in countries such as Yemen, and some medicines are sold well below international reference prices, raising concern about quality, authenticity and integrity of supply chains. The dominant role of the private sector as first line supplier of essential (and non-essential) drugs is not reflected in the policies of most countries. Limited public resources and oversight capacity is usually focused on the publicly controlled channels. International donor agencies also appear to be biased in favour of the public sector supply systems, using them to procure and distribute program drugs and focusing their technical assistance work on them rather than assisting the government in strengthening oversight of the private sector and improving capacity in contracting with the private sector as a means to ensure drug availability at the point of sale.

Ghana provides an interesting example in which, despite all the support given to the public sector supply system, healthcare providers increasingly source from private wholesalers which have set up better logistics systems and can provide delivery and payment terms that better match facilities' cash flow. This development was possible due to the increased financing for drugs available as a consequence of the health insurance roll-out. Ghana is now facing the choice to either make massive improvements to its public sector supply system or move on to a system of framework contracts with private providers, similar to the prevailing practice in OECD countries.

The example of Liberia shows how the public sector could use governance and management structures of the private sector to build a functioning supply system for essential drugs. Liberia's Community Outreach Pharmacies are a not-for-profit venture run by the agency in charge of public sector procurement and distribution. Its success is based on a simple business model that meets the demand of customers for high quality, affordable essential drugs. Framework contracting with an international, not-for-profit provider that has in-house quality assurance systems in place provides a higher safety margin on the quality side, in a country that lacks a functioning drug quality control lab and could have capacity problems enforcing the law against providers that sell sub-standard drugs. The public sector drug supply is largely donor dependent, making state-of-the-art logistics management difficult as supplies are hardly predictable. Scaling up the Community Outreach Pharmacy program and linking it with a de-centralized financing mechanism, for example a community based insurance system that includes a basic drug benefit package, could be a viable alternative to relying on a public sector administered program.

***Pervasive weaknesses in regulation:*** In all countries (with the partial exception of Indonesia), the medicines regulatory agencies report insufficient capacity to conduct many of their functions, especially lack of skilled staff; lack of financial resources, insufficient laboratory capacity and inadequate pharmacovigilance capacity. They also report difficulty in undertaking enforcement action associated with wider problems related to weak rule of law, inefficient judicial systems, under-resourced and/or politically over-ridden public sector litigation capacity. In addition, prescription drugs are reportedly able to be purchased without prescription (though in Peru, there is evidence that patients mostly follow doctor's advice). Compared to other countries assessed, Indonesia has made the most progress in building up credible regulation of manufacturing and product registration, but faces major challenges in a decentralized environment to regulate retail pharmacy, dispensing doctors and prescription patterns. As a result of actual and perceived regulatory deficiencies, in all the countries studied there is a lack of doctor and patient confidence in generics, and those who can afford it prefer to pay a premium to purchase originator products or "premium" reputable branded generics. There is a spectrum of problems in the regulation of medicines entering the drug market in most countries. Low income countries with fragile institutions such as Yemen and Benin face very serious quality and safety issues, and their prospects for creating well functioning regulation are limited. Even Peru, a middle income country with relatively strong institutions, faces very serious issues because of deficient medicines legislation that allows certain private importers to effectively bypass the regulatory process. Adoption of an appropriate law has been delayed and blocked repeatedly by deadlocked interest group politics.

### **Example: Policy and regulatory challenges in Benin**

As part of the country health sector analysis, the Beninese Ministry of Health (MOH) and its Directorate of Pharmacy and Drugs (DPD) requested (through the Bank's Task Team Leader) an analysis of governance and management issues in the current public supply systems of essential medicines. The overall policy objective was to improve supply chain efficiency and reduce out-of-pocket expenditures on drugs. The main issues identified in the assessment are listed below:

- On the policy level, there are delays in updating the 2000-2004 National Drug Policy and the 2003 essential drugs list, which makes it difficult to integrate changes demanded by vertical programs that use new protocols authorized on an exceptional basis
- The national regulatory agency - the Directorate of Pharmacies and Drugs (DPD), has extremely weak capacity: it employs only 3 qualified pharmacists and a few trained inspectors, none of them officially nominated. There appears to be limited political will to address the gaps in regulation – no legal action has been taken in recent times against pharmaceutical sector actors that break the law
- There is a large and growing informal drug market which operates openly without regulation of the quality of products entering the market. As a result, Benin is exposed to a high risk of sub-standard, counterfeit, expired, and diverted medicines being present in the market, especially from neighboring Nigeria
- The public sector warehousing and distribution system for essential medicines is inefficient, and the public sector is weak at quantifying drug needs, leading to simultaneous overstocking and stock-outs of essential medicines, especially in peripheral health facilities and remote areas
- High prices of drugs in formal public and private sector outlets explain why poorer people go to the informal drug market. A coefficient of 1,5 (public sector) and 1,78 (private sector) is applied to the drug factory price to cover distribution costs, but public and private health care facilities add high margins to make profit out of drug sales

The above findings from the assessment suggested a combination of weak capacity in core public functions (policy making, regulatory oversight, public supply chain) and limited political support for enforcing rules against a possibly powerful group of traders that operate outside the law. The illegal trade in counterfeit and sub-standard drugs has characteristics of organized crime and the potential to intimidate public officials who stand up to enforce the law. The example of the former head of the Nigerian drug agency, who was facing assassination attempts after cracking down on the counterfeiters in her country, demonstrate this unfortunate fact<sup>3</sup>. On this background, the willingness of MOH officials to investigate the problems and collaborate with international agencies is a positive sign for growing awareness and political will to address the issues.

***Inefficient public sector logistics systems and poor availability of essential drugs in the public sector:*** Peru and Indonesia have both achieved relatively good availability of essential drugs in public primary care facilities at low cost, by implementing policies such as adopting a well-founded Essential Drugs List and using low cost generics. Peru has also demonstrated the ability to achieve substantial price reductions

through centralized competitive tendering, facilitated by e-procurement systems. However, even in these two middle income countries, public sector logistics systems are functioning inefficiently. High availability has been achieved at a cost of high levels of inventory and excessive stocking, leading to waste of date-expired products. At the same time, there are some stock-outs of particular items. All other countries suffer from poor public sector availability of essential medicines, frequent and prolonged stock-outs, alongside overstocking and expiry of some products, due to inefficient logistics management. In these countries, insufficient budget to finance procurement of essential drugs is a major constraint. However, the fact that public sector supply chains demonstrate a pattern of overstocking and stock-outs even in the relatively well funded, higher capacity countries, highlights the inherent problems of bottlenecks and planning rigidity associated with centralized annual procurement of fixed volumes of medicines or commodities, and distribution through multi-level public medical stores. Much better availability is achieved in Indonesia's hospitals and in schemes in Ghana that use partnerships with contracted private pharmacies, though at higher prices. Some countries (such as Peru and Indonesia) that have undergone recent public financial management and procurement reforms to address legacies of high levels of corruption, are reluctant to adopt more flexible and responsive procurement systems or contract the private sector, fearing that this may create alternative channels of vulnerability to corruption. These findings highlight the limitations of hierarchical-control-based approaches to strengthening governance of functions that call for more flexible, agile systems, capable of handling greater complexity. There are some emerging lessons about how to combine the strengths of more flexible, delegated, decentralized or incentive-based approaches with the need for checks and balances, transparency and accountability. Using framework contracts to allowing more flexibility about volume ordered, and increasing frequency of delivery are simple starting points. A forthcoming World Bank study of West African reforms of traditional public sector central medical stores<sup>4</sup> finds that it *is* possible to devise effective governance arrangements for autonomous medical stores operating under more flexible financial and procurement rules, even in countries with generally weak institutions and high corruption risks. The study makes recommendations based on actual cases which achieved substantial improvement in performance of procurement and logistics systems, as well as increased transparency and accountability.

**Example: Establishing a secure supply chain in Liberia<sup>5</sup>**

Funding for a program to provide public clinics with essential drugs is very limited and stock-outs are frequent. To improve the supply situation, the National Drug Service (NDS) runs, separate from its core function as the main public procurement and distribution agency, three “Community Outreach Pharmacies”. These pharmacies are supplied from international procurement agencies with quality assured drugs, under a framework agreement between NDS and the agencies. Stock-outs are rare and prices for most items are lower than in private sector pharmacies. As a policy, drugs are dispensed in full treatment courses only. Public acceptance for the NDS pharmacies is high and a potential scale-up is under consideration. This example shows that even in an environment with very low capacity for logistics and regulation, it can be possible to establish secure supply channels for essential drugs, as an alternative strategy to an intervention that targets the underlying problem but may require much more resources and a longer time horizon.

*Numerous challenges are related to the control of pharmaceuticals benefits expenditure in expanding social health insurance schemes:* Ghana and Indonesia have recently implemented rapid extensions of social health insurance coverage, and both countries have encountered difficulties in controlling pharmaceuticals expenditure in the early phase of this expansion. However, there are lessons from successful control of pharmaceutical expenditure in some of the longer established social insurance schemes covered in the study – Indonesia’s civil service scheme (ASKES, see box below), for example. But both this scheme and Peru’s social insurance schemes face continuing challenges in influencing and enforcing doctor prescribing behavior to deter out-of-formulary prescribing. Financial incentives for unethical prescribing are pervasive in all the countries studied and derive both from industry marketing practices and from doctor-dispensing and doctor ownership of pharmacies. Ghana is implementing an electronic claim management system that allows detailed reporting on drug utilization and costs by institution. The challenge will be to ensure that the data entry is complete and reliable and to define management criteria in a way that makes good use of the data and maintains a good balance between treatment quality and costs.

**Example: Cost control in a health insurance scheme in Indonesia**

The social health insurance scheme for civil servants in Indonesia (PT ASKES) has a system for managing drug expenditure that could be seen as “good practice” for a developing country. Specific features are: a formulary based on independent and scientific advice; prioritization linked to budget availability; prescribing protocols for high cost drugs; competition to obtain discounted prices for drugs listed in its annual reimbursement list; publication of the price lists; payments to pharmacists based on fixed fees and regressive margins rather than a percentage mark-up

*Lack of consumer power and market failures characterize the pharmaceutical sector and influence consumption patterns:* As largely documented in the literature and confirmed in the current case studies, the pharmaceutical market (like other healthcare markets) is characterized by “market failure”, because ultimate clients do not have enough knowledge to make rational choices of treatment or assess the quality of the products they purchase. Financial incentives for providers are usually

not in line with rational treatment objectives, meaning that providers (such as drug companies, doctors and pharmacists) tend to use their position to influence what patients (and insurance systems) pay for. This can lead to the typical pattern of over-prescribing and use of expensive medicines instead of cheap ones that have the same efficacy. In resource-poor settings, limited patient purchasing power acts as a barrier against over-utilization of expensive treatments (the main problem is under-utilization and sub-optimal health outcomes due to delayed or lacking treatments). However, the introduction of third party payer systems in such a setting can lead to a significant increase in consumption and average costs per prescription.

**Example: Abuse of insurance benefits in Ghana**

Ghana has a health insurance system that covers roughly 50% of the population and pays for a range of essential drugs. Rules for providers are defined by a central agency, the National health Insurance Association (NHIA). The actual insurers are decentralized and partially autonomous district health insurance schemes. Some schemes have major problems with specific providers, who seem to exploit the reimbursement system by prescribing multiple, partially overlapping treatments for common diseases such as malaria. The same patient may get an injectable Artemisinin derivate and an oral ACT, an injection if a painkiller and an oral pain medication, an antibiotic and a multivitamin preparation. Claims officers try to rule in these practices but see resistance from doctors. Claim payments may be delayed and providers decide to stop accepting insurance patients unless they pay cash. NHIA is developing a computerized claim management and review system to assist individual schemes and back them up in the provider negotiations with tools to better identify and demonstrate abuse and fraud.

**Impact Assessment and Sustainability of Reforms**

As pointed out above, the assessments made in the eight countries discussed here were based on a perception that there is a need for change in how the pharmaceutical sector is governed or managed. Given the limited time between the assessments and the deadline for this report, impact assessment is restricted to a review how the results were received and which follow-up actions were taken to implement changes, respectively initiate a reform process if the competence of the executing authority was not sufficient to make the necessary corrections. In the perception of the client and the World Bank task team leaders involved, the approach was generally seen as successful. Assessment results were accepted as relevant and in most cases created new insights for the client. In all countries, there were follow-up discussions and in most cases a direct policy impact can already be seen in form of decisions that were made or work program that have been established since. The table below provides the main recommendations from the country assessments and the actions taken on the client side based on the assessment reports.

Table 2: Pharmaceutical sector assessment recommendations and follow-up

Country	Main recommendations	Follow-up actions
<b>Benin</b>	Capacity building in policy and regulatory functions; Consider setting up a secured private sector distribution chain with franchise drug stores	New drug policy finalized; two additional pharmacists hired by drug agency and WHO governance assessment finalized
<b>Ghana</b>	Improve management system at NHIA; strengthen NHIA role as main purchaser by contracting with suppliers (defined quality and price)	Ghana joined MeTA and set up a work program to improve transparency in the sector; NHIA implementing claim management system
<b>Indonesia</b>	Modify public budgeting and procurement rules to increase competition; strengthen oversight of poorly performing districts; apply expenditure management system from PT ASKES to other parts of insurance system; change payment systems in public hospitals to include drug costs	Findings were discussed with government in workshops and published in form of a policy note that informs new five year plan
<b>Liberia</b>	Establish drug agency and drug quality control lab; scale up Community Outreach Pharmacy (COP) program	Draft law for drug agency developed; consultancy for scaling up COP program under way, financed by Japanese Trust Fund
<b>Peru</b>	Pass new drug law that closes loopholes for non-regulated imports; upgrade supply chain to address problem of stock-outs and over-stocking	Peru joined MeTA as a pilot country and developed a comprehensive work plan to increase sector transparency and functionality
<b>Timor Leste</b>	Strengthen regulatory system; improve quantification system and supply chain management; use framework contracts for procurement and improve quality assurance (QA); strengthen SAMES board	Pilot for framework contracting with prequalified suppliers initiated; QA system improved; steps taken to strengthen SAMES autonomy; coordinated work program between donor agencies
<b>West Bank/ Gaza</b>	Strengthen regulatory oversight and separate responsibility for registration and inspection; create Essential Drugs List and promote rational use; develop pricing policy; strengthen QA and monitoring to fight counterfeits	Two workshops with government to discuss results; separate procurement department established
<b>Yemen</b>	Develop basic regulatory infrastructure and tools to provide functionality for registration and QA; develop transparent procurement system for public sector	Additional assessment of public supply chain was done subsequently; recommendations were used to prepare World Bank health project, providing assistance for establishing pilot logistics system in two governorates

## Conclusions

The work program financed by the Norwegian Governance Trust Fund has demonstrated that it is possible to carry out a rapid, low cost diagnostic assessment of the pharmaceutical sector with a focus on governance and management issues, tailored to country priorities and opportunities for change. The assessment requires expert guidance to recognize patterns that point towards specific underlying problems and come up with practical recommendations to improve results. These recommendations may or may not address the underlying problems directly. For example, if there are signs for institutional corruption in a given system, it may be more effective to strengthen management systems through automatic data collection and reporting that exposes corrupt behavior, than trying to confront the problem through the legal system. In working with World Bank health teams and external partners, the analytical approach made it possible to coordinate the outputs of the assessment with follow-on support from World Bank country programs and other donor-supported programs, including Medicines Transparency Alliance in Ghana and Peru and the Japanese Social Development Fund in Liberia.

The somewhat opportunistic approach to the selection of policy dimensions for each country study increases political relevance but may limit the scope for cross-country comparisons. Compared to the WHO tool, which has structured questionnaires and is implemented by a team of interviewers trained on using the tool but not necessarily knowledgeable enough to question or look behind the answers they obtain, our approach is a more political one that aims at catalyzing change. This is done by taking into account pre-existing conceptions among decision makers and trying to strengthen “champions of reform” by providing usable and credible information rather than comprehensive data sets. We found that our approach has advantages in countries that might be reluctant to open up to an analysis with a standardized tool explicitly focused on corruption vulnerability. Naturally, these tend to be countries with greater governance problems than those that would volunteer to be assessed with the WHO tool.

The common patterns of dysfunction and governance failure identified in the country assessments suggest a common toolbox of policy options for addressing the problems. Historically, developed countries have gone through a period with similar problems such as regulatory weakness, health risks from unsafe products, excessive pricing of drugs and inadequate use. Over the last 50 years, an increasingly converging set of policies has emerged that appears to be able to counteract market failure to some extent and increase access for most or all citizens to safe, reasonably priced drugs when needed.

The two key elements of good governance and management in the pharmaceutical sector of developed countries are

1. Credible, competent regulation on a background of a society that respects and enforces the rule of law
2. The emergence of third party payers that act as active purchasers, ending the provider dominance in the marketplace and using purchasing power to get supply security at reasonable prices and enforce more rational use of medicines

While all countries included in this study acknowledge the importance of regulation and make steps to improve their regulatory oversight of the sector (although starting from very different baselines), only a few currently have the capacity to develop third party payment systems that have the potential to change market dynamics. However, without such systems, there seems to be little hope for a major break-through in overcoming the problems related to market failure. If there is one key message from the work done in eight countries, it is that local authorities and donors should jointly work towards future financing systems that include a managed pharmaceutical benefit component, meaning a list of reimbursable drugs that patients can obtain for free or a small co-payment, while providers are paid based on agreed contractual terms that include price, quality and utilization criteria. The Ghana example demonstrates that such an approach is possible in a low income country, although there will be significant management challenges in the introduction period. Development partners may want to review their current access-to-medicines strategies and try a longer term view rather than putting too much energy into improving systems that build on a status quo of fragmented public sector service delivery with partially perverse incentives and lack of consumer empowerment. Ultimately, good governance and management need to be designed into systems instead of relying on enforcement only; both are not policy objectives per se, but should serve the purpose of providing better health services to vulnerable populations.

## References

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<sup>5</sup> Draft Liberia Mission Report February 2009; World Bank internal document; HDNHE

## **Annex 1: Framework for rapid assessment of the pharmaceutical sector in a given country**

(To be adjusted to the country context and scope of the assessment)

Version: August 2009

### Glossary:

EU	European Union
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HIF	Health Insurance Fund
IMS	Company that provides pharmaceutical market data in developed and middle income markets
INN	International Non-proprietary Name
MOH	Ministry of Health
NGO	Non-governmental organization
OEBIG	Austrian Health Institute
OECD	Organization of Economic Collaboration and Development
OTC	Over the Counter
PER	Public Expenditure Review
R&D	Research and Development
Rx	Prescription drugs
TRIPS	Trade Related Aspects of Intellectual Property Rights
VAT	Value Added Tax
WHO	World Health Organization

<b>Dimension</b>	<b>Sources</b>	<b>Questions, data requests</b>
Pharmaceutical market	IMS, industry associations, MOH, drug agency, HIF	<ul style="list-style-type: none"> <li>• Total market, retail/ex-factory prices</li> <li>• HIF paid market</li> <li>• Privately paid market Rx/OTC</li> <li>• Hospital market</li> <li>• Original brands versus generics</li> <li>• Presence of copies (of drugs still patented in OECD countries)</li> <li>• Rx share of cheapest generic per substance for some indicator drugs</li> <li>• Locally manufactured versus imported drugs</li> <li>• Existence and size of informal market, circulation of illegal drugs</li> </ul>
Pharmaceutical policy and regulation	MOH, drug agency	<ul style="list-style-type: none"> <li>• Existence of an integrated health strategy</li> </ul>

		<p>with pharmaceutical component</p> <ul style="list-style-type: none"> <li>• Existence of a national drug policy</li> <li>• Relevant legislation combined in one drug law</li> <li>• Detailed by-laws governing all regulatory matters</li> <li>• Independent drug agency with adequate resources</li> <li>• Quality control lab with sufficient capacity, certified under GLP</li> <li>• Enforcement capacity for GMP, in-market quality surveillance and pharmacovigilance</li> <li>• Stakeholder representation in relevant commissions and other bodies (including consumers)</li> <li>• Publication of proceeds/minutes by relevant commissions</li> <li>• Trade regulation (industry, wholesale and retail level), licensing, accreditation</li> <li>• Implementation of patent rights, use of patents by industry</li> <li>• Legal basis for Compulsory Licensing based on TRIPS exemptions</li> <li>• Legal basis for prosecution of counterfeiters</li> <li>• Anti-counterfeiting strategy</li> <li>• Regulatory partnerships/projects with other countries or international bodies (EU, WHO)</li> </ul>
Public and private drug expenditure	MOH, HIF, PERs, household surveys, OECD databases, World Bank internal sources	<ul style="list-style-type: none"> <li>• Drug expenditure by HIF, MOH and other public payers</li> <li>• Other segments such as special disease programs</li> <li>• Top 20 products paid for by HIF</li> <li>• Regional pattern of expenditure</li> <li>• Expenditure by age group, income level, type of disease</li> <li>• Private out-of-pocket expenditure for co-</li> </ul>

		<p>payments; exemptions</p> <ul style="list-style-type: none"> <li>• Household expenditure for cash purchases of Rx and OTC drugs</li> <li>• Tracking of public drug expenditure – does central purchasing match what is dispensed at clinic level?</li> <li>• NGO or other non-public, donor financed drug expenditure</li> <li>• Private insurance drug expenditure including corporate employee health plans</li> <li>• Total, public and private per-capita expenditure</li> <li>• All data over 3-5 years with trends</li> </ul>
Drug pricing	MOH, drug agency, HIF, industry associations, retail pharmacy, WHO, literature, OEBIG, IMS	<ul style="list-style-type: none"> <li>• Pricing system, regulation for patented drugs, generics and OTC</li> <li>• Reference pricing mechanisms</li> <li>• VAT and other taxes</li> <li>• Wholesale and retail margins</li> <li>• Deviations between list prices and actual prices (rebates, free goods, payment terms)</li> <li>• Transparency of pricing for patients</li> <li>• Price levels compared with other countries</li> <li>• Co-payments, dispensing fees</li> <li>• Special access programs, for example company-issued patient cards</li> </ul>
Purchasing, reimbursement and procurement	HIF, hospital pharmacy, retail pharmacy, pharmacist associations, MOH and other buyers	<ul style="list-style-type: none"> <li>• Purchasing decisions in public and formal private sector – who defines what is purchased?</li> <li>• Reimbursement mechanism – direct to pharmacy or patient pre-payment</li> <li>• Reimbursement levels</li> <li>• Selection of drugs for reimbursement lists, drug formularies</li> <li>• Pharmaco-economic assessment for reimbursement decisions</li> <li>• Procurement mechanisms used by different buyers (transparency, effectiveness, efficiency)</li> </ul>

		<ul style="list-style-type: none"> <li>• Quality controls as part of procurement</li> <li>• Provider incentives related to quality and price (how competitive is the market?)</li> <li>• Preference for local manufacturers</li> <li>• System abuse and corruption risks in opinion of different stakeholders</li> </ul>
Service delivery and logistics	MOH, Central Medical Stores, wholesalers, hospitals, pharmacy	<ul style="list-style-type: none"> <li>• Existence of a public service delivery/ distribution mechanism</li> <li>• Planning and management tools and accountability (forecasting, budgeting, transparency)</li> <li>• IT system, logistics software</li> <li>• Performance measurement</li> <li>• Contracting with private sector: scope, terms, enforcement, data flow and management</li> </ul>
Industry and trade	Industry and professional associations, retail pharmacy	<ul style="list-style-type: none"> <li>• Number and main role of industry associations</li> <li>• Size and competitive position of national industry (local market, export)</li> <li>• R&amp;D activities of industry</li> <li>• Local subsidiaries of multinational firms</li> <li>• Manufacturing and licensing agreements between international and national companies</li> <li>• Political influence of industry (national and international)</li> <li>• Manufacturing standards of local industry</li> <li>• Forward integration (industry-wholesale)</li> <li>• Number of wholesalers, market share of top five</li> <li>• Number of retail pharmacies absolute and per capita</li> <li>• Rx enforcement in pharmacies</li> <li>• Existence of informal sector (manufacturing, wholesale, retail)</li> <li>• Capitalization of wholesalers and pharmacies</li> <li>• Share of publicly paid Rx business in total</li> </ul>

		pharmacy income
Rational use of drugs	HIF, professional associations, literature, industry, retail pharmacy	<ul style="list-style-type: none"> <li>• Prescription guidelines for doctors</li> <li>• IT system for monitoring of prescription/dispensing with central data collection in real time and routine analysis of defined parameters for rational use</li> <li>• Perceptions about drug quality in various market segments among doctors and consumers</li> <li>• Influence of belief systems and traditional medicine on care seeking behavior</li> <li>• Education for professionals and consumers on use of medicines</li> <li>• Incentives for doctors, pharmacists and patients</li> <li>• Marketing strategies of industry and wholesalers; sanctions for unethical marketing practices, application of ethics code (IFPMA, EFPIA or similar)</li> <li>• Brand or INN based prescription</li> <li>• Are doctors required to inform patients on co-payments, cheaper options?</li> <li>• Do pharmacists have substitution rights?</li> </ul>

## **Annex 2:**

### **Main Findings and Recommendations from Country Reports**

As a result of the choice of a neutral instrument for the sector assessment, the findings in the different countries and the conclusions include aspects that are related to capacity, management quality and governance. The weight of the different aspects obviously differs between countries. The specific recommendations that were made based on the assessment reports focused on ease of implementation and likelihood to improve outcomes rather than going directly at the likely causes, which is sometimes not politically viable.

#### ***Benin***

As part of the country health sector analysis, the Beninese Ministry of Health (MOH) and its Directorate of Pharmacy and Drugs (DPD) requested an analysis of governance and management issues in the current public supply systems of essential medicines. The overall goal was to improve efficiency and impact on health outcomes and reduce out-of-pocket expenditures on drugs.

#### *Main findings*

- The national regulatory agency - the Directorate of Pharmacies and Drugs (DPD), has extremely weak capacity: only 3 qualified pharmacists, a few trained inspectors, none of them officially nominated. There appears to be limited political will to address the gaps in enforcement – no legal action has been taken against pharmaceutical sector actors that break the law
- There is a large and growing informal drug market, which operates openly without regulation of the quality of products entering this market. As a result, Benin is exposed to a high risk of sub-standard, counterfeit, expired, and diverted medicines being present in the market, especially from neighboring Nigeria
- The public sector warehousing and distribution system for essential medicines is inefficient, and the public sector is weak at quantifying drug needs, leading to simultaneous overstocking and stock-outs of essential medicines, especially in peripheral health facilities and remote areas
- The MOH is experiencing delays in updating the 2000-2004 National Drug Policy and the 2003 essential drugs list, which makes it difficult to integrate changes demanded by vertical programs that use new protocols authorized on an exceptional basis
- High prices of drugs in formal public and private sector outlets explain why poorer people go to the informal drug market. A coefficient of 1,5 (public sector) and 1,78 (private sector) is applied to the drug factory price to cover distribution costs, but public and private health care facilities add high margins to make profit out of drug sales.

#### *Recommendations for follow-up*

- Strengthen the legal and regulatory environment as a basis for transparency in the sector, including finalization of the new pharmaceutical and drug policy, based on evaluation findings and numerous reviews; reinforce the capacity of the DPD to fulfill its mandate through capacity building and hiring of more pharmacists within the country health system

- Effective capacity building of staff at central and peripheral levels in both the public and private sectors, especially in areas of quantification, forecasting and good management practices
- Revamp the fight against the illicit drug market: combining educational activities targeting the general public, promotion of generic drugs and repressive action against illegal drug vendors; consider setting up low-price, generic franchise pharmacies in high traffic areas similar to the Liberian model
- Greater accountability and transparency in the public sector procurement and supply chain management. An internal assessment of good governance and transparency in the pharmaceutical sector has been conducted with WHO support and its draft report is being finalized to be shared with all partners

A follow up mission in February 2009 found that some progress has been made: the new national pharmaceutical and drug policy was finalized, two new pharmacy graduates were hired in the DPD and the WHO governance assessment has been completed.

## *Ghana*

The assessment in Ghana was requested as part of the World Bank's support for the National Health Insurance Agency (NHIA) with a focus on governance and management challenges in the drug benefit component of the National Health Insurance Scheme (NHIS). This assessment was done as part of a wider pharmaceutical sector assessment in November 2008.

The main findings were that medicines are the major driver of costs per claim for outpatient visits under the NHIS, while the NHIA and the district mutual schemes under the NHIS are lacking tools to control drug prices, influence rational use, control volume of drugs prescribed, and detect fraud and abuse by providers or patients

Supported by the World Bank project, the NHIA put in place some tools that have the potential to improve control, such as a formulary based on the Essential Drug List with reimbursement prices based on median prices observed in the market, as well as prescribing guidelines for common conditions. NHIA is also implementing an IT system that should provide a platform for using data mining algorithms to detect indications of irrational use, over-use and fraud by patients or providers. It will be important to monitor, review and refine these tools over time.

Additional tools for control and management could be considered to control volume of prescriptions and reduce "polypharmacy". The assessment report suggested setting condition-specific contractual limits on outpatient visits and numbers of drugs prescribed, combined with a public education campaign. Another option is inclusion of drugs costs within a future DRG-type payment system. Facilities could be offered incentives for improved prescribing behavior (e.g. reduction in proportion of patients prescribed antibiotics; increase in proportion of hypertensive patients prescribed low cost first line drugs). In the medium term, consideration could also be given to introducing a small copayment or dispensing fee for prescriptions, which was deemed politically not appropriate prior to the elections in 2008.

As a pilot country for the Medicines Transparency Alliance (MeTA), Ghana could take advantage of the resources provided and support NHIA in developing price monitoring capacity. MeTA could also encourage publication of price information, development of drug quality monitoring mechanisms and sharing of quality information. An ongoing study on the quality of antibiotics in circulation is one outflow of the MeTA participation.

Instead of trying to control drug prices via reimbursement ceilings, NHIA or the Ghana National Drugs Program could enter into framework contracts with private suppliers to ensure availability of good quality, low price generics at contract facilities. A special situation is created by the “Affordable Medicines Facility-Malaria” (AMFm), which will reduce prices of Artemisinin-based Combination Therapies (ACTs) in Ghana – currently responsible for a significant share of the drug costs under health insurance. NHIA is likely to play a key role in monitoring prices of ACTs under the initiative and to ensure subsidies are transmitted to end-users.

Given the substantial increase in drug funding available due by health insurance, private sector investment in nationwide distribution of medicines could be encouraged by contracting out some of the responsibilities currently held by the Central Medical Store. This could include a private sector initiative to collect medicines market data (analogous to the work of IMS in upper income countries) to facilitate more efficient market operations.

In summary, the assessment work in Ghana was fully embedded in ongoing developmental work and led to a productive dialogue on practical solutions to improve governance and management capacity. The partnership with MeTA suggests that the achievements are sustainable and will lead to further improvements driven by local stakeholders.

## ***Indonesia***

The Ministry of Planning (“Bappenas”) and Ministry of Health requested a pharmaceutical governance assessment as an input into the Government’s next five year strategic plan for the health sector, with a particular focus on: (i) management of pharmaceutical budgets on by national and local governments, including planning, budgeting, procurement, distribution, buffer stocks management, and role delineation between national and district government and (ii) the mechanisms for control of pharmaceutical expenditure by social health insurance schemes. The latter request was based on rapid growth in medicines expenditure by a new health insurance scheme for the poor (“ASKESKIN”), which is part of Indonesia’s plans to move towards universal SHI coverage in the next 5 years.

### *The main findings of the assessment*

- Although public procurement prices for unbranded generics are low, there are high but hidden and un-quantified costs of holding very high levels of inventory at central, provincial, district levels in public sector drug warehouses, combined with stock-outs of some drugs and vaccines in some facilities. These problems arise for several related reasons: a complex mix of centralized planning, budgeting and procurement, coordinated with local planning and procurement is used, which is not sufficiently responsive to local

variation in demand for medicines. This planning is made necessary by a rigid, highly compressed annual procurement cycle at national and district level. Idiosyncratic procurement regulations and very low procurement price ceilings for many unbranded generic drugs have impeded competition in public tenders, entrenched monopolistic supply of unbranded generics by state owned enterprises, and resulted in failures of bidding in remoter districts with high transport costs and lower volumes

- Some district governments allocate too little budget to essential medicines for primary care, have poor availability of medicines in their primary care networks, and perform poorly in procurement and logistics management
- The social health insurance scheme for civil servants (PT ASKES) has a system for managing drugs expenditure that has many good practice features: a formulary based on independent and scientific advice, prioritization linked to budget availability; prescribing protocols for high cost drugs, competition to obtain discounted prices for drugs listed in its annual reimbursement list, publication of the price lists, payments to pharmacists based on fixed fees and regressive margins rather than a percentage mark-up
- Likely causes for the rapid escalation of public spending on hospital drugs under the ASKESKIN SHI program for the poor in 2006-2007 are poor control of membership, lack of control of drug prescribing outside the formulary or of quantities prescribed, and lack of fraud control. It is too soon to assess the limitations on the drugs benefit package introduced by MOH in 2008 under a revised insurance scheme for the poor. However, this experience demonstrates that the challenges for scaling up the type of drug expenditure management system PT ASKES operates to cope with a much larger membership are substantial and will require sufficient resources to be devoted to transition planning and systems development
- Private out-of-pocket spending on medicines will continue to dominate the sector for some years to come and deserves policy attention. Over half of this market is in the hands of unlicensed drug sellers and dispensing doctors – although doctor dispensing is illegal except in rural areas. Quality control and irrational use of drugs are major concerns in these segments of the market
- Indonesia has already carried out the WHO assessment of vulnerability to corruption in the pharmaceutical sector. Surprisingly, in the light of information provided to us by key sector informants for our assessment, the only issues of concern highlighted in the WHO assessment were lack of documentation of some procedures, and the inclusion of some traditional medicines in the essential drug list without an objective scientific basis. WHO/HAI also supported a price comparisons survey in Indonesia, carried out by a research center of the MOH, which provided evidence of low public procurement prices for unbranded generics, and of high hospital and private pharmacy prices for the most commonly sold branded generics and originator brands as a multiple of the cheapest available generic

#### *Recommendations for follow-up*

- Revision of budget and procurement rules affecting pharmaceuticals: changes to public procurement regulations for drugs and some related aspects of budget regulations are needed to increase competition between suppliers of branded and unbranded generics, to transform the central procurement and logistics system into a “pull” system with more flexible volume contracts and

more frequent delivery to reduce inventory levels and costs. Once this reform has been put in place, the MOH could offer a pooled procurement service to district governments to help them reduce the transactions costs and risks of local procurement. This recommendation was discussed with the WB procurement staff for Indonesia, and could be followed up in their future engagement with the GOI authorities on public financial management

- The central government authorities could articulate more clearly the responsibilities of local governments to finance essential drugs from their budgets. At the same time, it could strengthen its influence over poorly performing districts by including one or two indicators of expenditure and availability of essential drugs in the set of local government indicators monitored by central government. The MOH could target technical support and supervision for medicines management to poorly performing districts
- The drug expenditure management used by the SHI scheme for civil servants could be considered for adoption by other parts of the SHI system when the new law on universal SHI is implemented
- The JAMKESMAS SHI program for the poor could develop methods of paying hospitals that include the costs of drugs within the price for in-patient services, alongside measures to strengthen hospital managers' capacity to control drugs expenditure and deter "outside formulary" and "outside hospital" drug purchases by in-patients

The findings and recommendations were discussed in workshops with Bappenas, MOH and other government authorities involved; representatives of industry and professional associations and academia. The findings were published and disseminated more widely in a policy note – one of a set of policy notes providing input to the Government's next five year strategic plan.

## ***Liberia***

The Ministry of Health (MOH) requested the support of the World Bank to follow up on a consultancy organized by the EU in 2007, which delivered a detailed pharmaceutical sector assessment, and verify to what extent recommendations have been implemented. The main focus was on regulation and systems that improve governance in the sector.

### ***Main Findings:***

- Significant progress has been made by the MOHSW to set up a functional legal and regulatory framework, with support from donors (mainly USAID) and neighboring countries (Ghana). As an interim step towards an independent regulatory agency, a Liberian Medicines Regulatory Committee was established, reporting to the Pharmacy Board. In the meantime, the legislation required to establish an autonomous government regulatory agency has been drafted and is expected to be passed in the near future
- Progress has also been made in public sector procurement and supply chain management, in particular by the National Drug Services (NDS), responsible for procuring and distributing drugs to public health facilities. Extensive technical assistance was provided by external partners and once fully deployed, the newly built capacity at NDS should also benefit other programs managed by NDS. A specific procurement regulation for drugs and medical products was drafted and approved, enabling NDS to use adequate

procurement methods for drugs such as framework agreements in form of Memoranda of Understanding with international procurement agencies to respond more flexibly to needs from its clients

- The Government is implementing programs aimed at increasing access to medicines, the “Free Drugs Program” and the “Community Outreach Program”, but they are limited in geographical coverage and cannot yet ensure regular access to quality essential drugs for the majority of the population
- Liberia has insufficient capacity for drug testing and limited drug quality control enforcement: the government has no control over the activities of private pharmacists and drug sellers other than trying to enforce minimum standards for shop size, location, and storage conditions through the Pharmacy Board; as a consequence, it is possible that a significant percentage of drugs sold in private pharmacies and drugstores might be sub-standard or counterfeit

#### *Recommendations for follow up*

- Accelerate the adoption by Parliament of the legislation required to establish the “Liberian Medicines and Health Products Regulatory Authority (LMHRA)”
- Scale up the Community Outreach Program, setting up additional NDS Pharmacies including a “pharmacy on wheels” serving rural areas where people meet on market days. Based on the assessment, funds required for drafting a detailed plan for the scale-up and organizing stakeholder consultations could be obtained from a Japanese Trust Fund.
- Set up a drug quality control lab, ideally in collaboration with the School of Pharmacy; and build capacity for inspection, sampling of drugs, testing and policing violations of the law, once the basic regulatory structures are in place

The findings were reported to the government and other donors. They led to a proposal to a Japanese Trust Fund that provides financing for a feasibility study and development of a business plan to scaling up the COP program. In parallel, with support from USAID the draft for a new law defining the role of a drug regulatory agency was developed.

### ***Peru***

The DIGEMID - the Peruvian Ministry of Health’s (MINSa) directorate responsible for medicines policy and regulation asked for a broader pharmaceutical sector governance assessment, alongside discussion of specific proposals for measures to improve transparency and strengthen efficiency and control over public expenditures, procurement and logistics management for essential medicines.

#### *Main findings*

- The electronic bidding system for centralized public procurement of medicines achieves very low prices. But, as in Indonesia, the rigidities of centralized planning and logistics are leading to accumulation of high levels of inventory in the public sector supply chain of MINSa, combined with some stock-outs. The problems are most serious in the peripheral rural facilities.
- Peru lacks adequate control over entry of counterfeit and sub-standard products into the market due to unusually low legal barriers for product registration. This leads to lack of confidence in generics, which undermines

price competition in the private sector and increases reliance on originator brands or expensive branded generics.

- The Peruvian authorities have introduced many of the foundations for good governance and transparency in the operations of government in general. A number of these are being implemented in MINSA and DIGEMID. However, some of the product registration and procurement rules and procedures, even if transparent, are too rigid, leading to inefficiency in use of public funds and performance problems in delivery of public services.

#### *Recommendations for follow up*

- Improve the supply chain to address the problem of stock outs and overstocks, by modifying the procurement and contracting process, as well as upgrading the skills and incentives of staff in peripheral health facilities, to make the supply chain more of a responsive “pull” than a rigid “push” system.
- Adopt the new pharmaceutical law that has been under debate for some time, blocked so far by the commercial interests of some importers with political connections

Peru has decided to participate as a pilot country in MeTA. The World Bank team was able to coordinate its work on the assessment with MeTA and provide input for the MeTA work program, which is expected to pick up some of the recommendations from the assessment report.

#### ***Timor Leste***

SAMES (Autonomous Drug and Medical Equipment Service) and the Ministry of Health (MOH) Pharmacy Department requested a rapid assessment of institutions involved in medicines and health commodities procurement financed by the Government of Timor Leste (GOTL) and donors. The government asked for practical recommendations, including advice on how to implement supplier prequalification and framework contracting.

#### *Main Findings*

- Key elements of drug policy and a legal/regulatory framework have been put in place. There are some promising developments in pharmaceuticals management, but as yet no comprehensive national drug policy. Timor Leste faces severe challenges and capacity constraints in implementing the policies it has adopted. There are no pharmacists in the public sector and the MOH’s Pharmacy Department has only 2 staff. In addition, most medicines in the country are not yet subject to registration or quality assurance
- The public sector supply chain has faced chronic delays in procurement and stock outs that impede availability of essential medicines, though there have been recent improvements (with recent field visits finding over 85% availability in SAMES and 70-90% of 10 tracer drugs available in facilities). Causes of delays include: failure to implement SAMES autonomy decree so that it cannot operate; key positions in SAMES are not filled; it cannot retain revenue from drug sales; it is not fully capitalized; it is bound by low GOTL procurement thresholds per cycle; past late payment has reduced the number of suppliers willing to bid. Emergency procurement with GOTL funds has been used to fill gaps where international procurement using donor funds has

been delayed because of capacity constraints, problems with overseas payment and opening letters of credit

- There are weaknesses in governance structures and practices in SAMES: Directors are not independent and are involved in daily operations; the Fiscal Commission that supervises financial management has not been appointed, nor has the MOF representative on its Board; there is inadequate separation of duties; there is insufficient checking of goods received in stores
- There are weaknesses in quality assurance for publicly procured drugs – such as failure to check authenticity of documentation, and lack of quality control when goods are received. QA policies have been planned but not yet implemented. There are instances of mislabeled drugs and suspected counterfeits being procured
- Quantification is difficult because of chronic shortages, and because of cumbersome aggregation of orders at district level. There is a need for more flexibility in ordering (facilitated by Framework Contracts) and more frequent delivery
- Donated drugs are present that breach guidelines; there are expiry date problems with donated drugs, especially of vertical program drugs. There have also been gaps in donor funding for essential drugs

*Recommendations for follow up*

- The MOH should improve the management capacity and leadership at the MOH Pharmacy Department to strengthen the regulatory system, lead the process of designing the national drug policy, manage the revision of the essential drug list, coordinate the technical assistance offered or planned for the subsector, and mentor new pharmacists to be recruited in the country.
- MOH should strengthen the drug registration system, make the Pharmaceutical Activities Regulation Commission (CRAF) operational and explore the possibility to refer to drug registrations by countries with stringent regulatory authorities
- The Pharmacy Department should establish a goal for drug availability and request district drug management to provide accurate data on availability of tracer drugs.
- The quantification committee proposed by SAMES should be put in place by MOH and include all key stakeholders and potential clients / partners involved in the procurement, storage and distribution of drugs to conduct a quantification exercise
- Governance and management of SAMES should be strengthened through the appointment of positions in the Fiscal Board, selection of an external auditor, and finalization of the capitalization study
- Procurement by SAMES should be based on framework contracting and reinforce quality assurance (QA) through prequalification of suppliers and products, the inclusion of QA conditions throughout the procurement and supply chain management process
- The essential drug list and standard treatment guidelines should be finalized as a basis for rational drug use

The findings were discussed in consultative meetings with the Pharmacy Department and SAMES, who found the technical advice and discussion helpful: this has led to a

decision to have regular technical consultative meetings. A follow up mission 3 months after the initial assessment found that action had been taken already on some recommendations. Good progress has occurred in SAMES procurement, which is piloting framework contracting to adopt flexible arrangements with a set of prequalified suppliers to cover the majority of essential drugs. Tender documents now include appropriate quality terms in bidding documents and SOPs for using a minilab for quality testing of drugs received, backed up by a WHO collaborating pharmaceutical testing center. A regional laboratory has been identified to contract for quality testing for suspicious items already in circulation. Some steps have been taken towards fully establishing SAMES as an autonomous service, though more steps are still required. The assessment and recommendations have been coordinated with the work of the World Bank health team and European Union, and with the Bank team doing the Country Procurement Assessment Report to ensure coordinated donor support, and linkage to the Joint Annual Sector Review. There will be regular monitoring meetings and visits.

### ***West Bank Gaza***

The West Bank Gaza (WBG) Ministry of Health (MOH) and its General Directorate of Pharmacy, which has functions in both Gaza City and Nablus requested a broad pharmaceutical sector governance assessment, directed at generating medium and longer term recommendations for improving policies, regulations and their implementation.

#### ***Main Findings***

- Medicines are a high and fast growing share of public expenditure on health; shortages are experienced in MOH facilities a few months after each bi-annual procurement cycle. Out of pocket spending on health is high, and about half is for medicines. Provision through United Nations Relief and Works Agency for Palestine Refugees (UNRWA) is higher in Gaza Strip (GS), where stock outs are less common and private spending on medicines is lower. Management of central and peripheral medical stores is not systematic. Procurement and inventory control is not fully computerized, and audit of procurement and CMS is not published.
- MOH public procurement prices are high compared to international comparators and UNRWA prices, due to lack of competition and potential for collusion in many items. Agents have exclusive contracts for branded medicines. Private sector prices are highest because the level of price control at the importer and wholesaler level is rather limited and the basis for the claimed add-ons and profit mark-ups remains unclear. NGO providers have a confusing variety of policies about the prices they charge and subsidies they offer for drugs
- There have been increasing instances of counterfeit or substandard drugs found in the market. Recent clarification of product registration requirements will provide a foundation for addressing quality concerns, but the MOH lacks post-market drug quality surveillance and sufficient pharmaceutical inspectors, and the University Laboratories it contracts for drug quality control do not have capacity for complex testing that is required for some products such as cancer drugs and hormones.

- The Essential Drug List needs review; non-rational use of medicines is widespread, such as “polypharmacy”, over-prescription of antibiotics and over-use of injections. Treatment guidelines exist but are not widely used and unethical drug promotion activities are not regulated.

#### *Recommendations for follow up*

- Strengthen the legal and regulatory framework and capacity for medicines registration: separation of drug registration and inspection into separate departments to create checks and balances within the systems for medicines regulation and public sector supply; systematic registration of all drugs by suppliers and manufacturers in WBG using a transparent and streamlined procedure.
- Adopt measures to promote rational use of drugs, including adoption of an essential drug list and drug promotion regulation to reduce unethical and excessive promotion of selected medicines
- Define and implement pharmaceutical pricing policies, which focus on improving affordability, and adopting transparent methods for setting price ceilings for public procurement
- Strengthen drug quality assurance and control and tackle the growing issue of drug counterfeiting. Proposed measures include full enforcement of GMP compliance, increased capacity for inspection and pharmacovigilance as well as post marketing surveillance to identify substandard drugs

As a consequence of the policy dialogue, the government established a new procurement department within the Ministry of Health.

### ***Yemen***

The main clients in Yemen were the Honorable Minister of Public Health and Population (MoPH) and the General Director of the Supreme Board for Drugs and Medical Appliances (SBDMA). They requested a broad assessment of the quality of the governance and management of the pharmaceutical sector in Yemen in order to provide feedback to other decision makers and stakeholders on how to potentially improve governance in the sector, with the ultimate goal of enhancing the affordability and improve overall accessibility of quality medicines.

#### *Main Findings*

- Public spending on essential medicines is among the lowest in the world (US\$0.50 per capita per year), leading to severe and longstanding shortages of essential medicines in the public sector; but the level of spending and selection of publicly supplied medicines fluctuate depending on donor priorities and unstable government priorities. Basic priority setting via an appropriate essential drug list is not implemented
- There is fragmentation of public sector procurement and logistics, stock outs are pervasive, though there is overstocking of some items leading to waste through destruction of expired products. Storage conditions in the multiple public medicines stores are very substandard
- Private sector availability is better, but prices of innovator and some branded generic products are a high multiple of MSH reference prices

- Substandard and fake drugs have been entering the market without quality control checks. There are no comprehensive laws and regulations governing medicines to provide a basis for dealing with offences, and the inspectorate lacks adequate trained staff, budget, mandate and standard operating procedures to carry out systematic post-marketing surveillance
- The local manufacturers are officially GMP-certified, but in practice a number are known to breach GMP standards and/or to market unregistered products. It supplies 10% of the local market by value and also exports its products, mainly generic sildenafil (Viagra)
- There is internal resistance to implementing a complex set of policy and institutional changes that needed to address the multiple governance deficiencies in the pharmaceuticals sector, because of their significant political consequences

*Recommendations for follow up*

- Define a new national drug policy and adopt the necessary laws and regulations to strengthen pharmaceutical management systems to support public health services and expand access to and improved use of essential medicines.
- Adopt an organizational structure with appropriate resources that ensure accountability, good governance and effective management practices. The structure should mitigate any conflict of interest and assure complementarities
- Establish transparent registration and licensing procedures that apply uniformly throughout Yemen and leave no room for individual discretion
- Develop a modern model of quality assurance and quality control for manufacturing (enforcement of compliance with GMP requirements), procurement (prequalification of products and manufacturers), storage and distribution of pharmaceutical products, including post-market drug quality monitoring
- Adopt drug financing and cost containment measures aimed at increasing efficiency in utilization of scarce resources and equity in meeting patient's needs. These include the development of a clear documented coverage, pricing and support policy, integrated with consistent budgeting, planning and procurement procedures that lead to timely and cost-efficient delivery, the promotion of generic drug use, regular drug pricing reviews (especially for branded, imported medicines), and monitoring of doctors' prescribing behaviors
- Maximize the purchasing power of available funds by establishing a procurement administration responsible for adherence with international national procurement rules and essential drug list concepts and development of a transparent purchasing and supply system. Procurement, storage and / or transport could be contracted out to specialized agencies or private sector providers working under supervision of the government. Thus, the potential for fragmentation, duplication, monopoly and collusion will be mitigated. The creation of an appropriate storage infrastructure at central and peripheral levels can benefit from existing facilities built under the previous World bank-funded project

The assessment produced a report for the World Bank Health Team to guide their future engagement in the pharmaceuticals sector. It was followed up by a more

specific review of the medicines logistics management system in the public sector, which recommended phased actions to tackle identified deficiencies in procurement and distribution of essential drugs, contraceptives, and medical, non-medical, and laboratory equipment and other related health commodities. The World Bank's health team is preparing a health project in Yemen, and plans to offer follow-up support in the form of technical assistance to help the authorities design a performing logistics system to be implemented in targeted project sites (Governorates of Aden and Sana'a).





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