IMPROVING TRANSPARENCY IN THE PHARMACEUTICAL SECTOR: REPORT ON THE STUDY TO IDENTIFY AND STRENGTHEN DECISION POINTS AGAINST CORRUPTION IN ALBANIA

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BY

MICHELE FORZLEY, JD, MPH
DIRECTOR
FORZLEY & ASSOCIATES

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DISCLAIMER

The findings of this study and recommendations are the result of scores calculated according to the World Health Organization methodology. The quantitative scores in this report are derived from the formula provided by this methodology. Qualitative interviews and desk research provided the balance of the information reported. None of the scores are comments attributable to any one person or informant.

For any questions on this study and its findings, please contact its author:
Michele Forzley
mforzley@comcast.net
1-301-565-0680

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ABBREVIATIONS USED IN THIS REPORT

CIF	Cost, Insurance and Freight
COI	Conflict of Interest Law
DC	Drug Commission on Drafting and Reviewing the Reimbursement List
DPC	Drug Pricing Commission
DPL	Development Policy Loan
EMEA	European Agency for Drug Control
EML	Essential Medicines List
EU	European Union
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GOA	Government of Albania
HII	Health Insurance Institute
INN	International Non-proprietary Name
KNB	Komisioni I Nomenklatures se Barnave
MOH	Albanian Ministry of Health
OECD	Organization for Economic and Development Cooperation
OTC	Over The Counter
QKKB	National Center for Drug Control
SOP	Standard Operating Procedures
TC	Tender Committee
TUHA	Mother Teresa Hospital – University Hospital Medical Center

IMPROVING TRANSPARENCY IN THE PHARMACEUTICAL SECTOR: A STUDY TO IDENTIFY AND STRENGTHEN CRITICAL DECISION POINTS AGAINST CORRUPTION

"The real crime is not the bribe. It is that patients do not get the drugs they need."
        Anonymous

"We try never to forget that medicine is for the people. It is not for profits.… [I]f we have remembered that, [the profits] have never failed to appear. That's another way of saying, do the right thing and the rewards will follow."
        George Merck, founder of Merck

EXECUTIVE SUMMARY OF FINDINGS AND RECOMMENDATIONS

DEFINING CORRUPTION AND WHAT TO DO ABOUT IT

In reading this report, it is important to keep in mind that the word corruption can be descriptive of behaviors and conditions. Behaviors can include bribery, fraud, favoritism, collusion embezzlement. The conditions can mean failures in the procedures of the pharmaceutical system either because no procedures exist or if they do they are too weak to provide guidance to those involved. When coupled with low or no moral standards the system can be vulnerable to corruption.

This report will describe that the Albanian pharmaceutical system is vulnerable to both corrupt behavior and corrupt conditions. This report recommends that full attention is focused on the conditions that represent weak or insufficient processes and at a few points, full out prosecution of criminal and illegal behavior is recommended. The capture of a few criminals will not result in the GOA being able to deliver safe, efficacious and cost effective access to drugs to its citizens unless corrupt conditions are remedied. Albania has already taken substantial steps in this direction by enacting a new national procurement law, recent actions by the Minister of Health and other steps. These efforts have already demonstrated their beneficial effect. This report emphasizes other procedural steps, many of which will require no more than simple changes to the existing system, such as translating the Albanian laws on drugs to English and posting them on the website.

The purpose of this study was to calculate a base line of where the system is in 2007. Guidance from the World Health Organization *Good Governance for Medicines* project and global health reform best practices recommends two phases of work to follow this assessment. The first is to establish a consultative process to develop and implement national frameworks to promote good governance in the sector. This report recommends numerous specific areas on which this process can be focused. The third step is to train all involved in the sector on the new framework.

WHY IS IT IMPORTANT TO UNDERSTAND THE VULNERABILITY TO CORRUPTION IN THE PHARMACEUTICAL SECTOR?

No health system can function without pharmaceuticals, the cost of which represents a major portion of public health expenditure in all countries. In developing countries, where most of the cost is borne by patients as out of pocket expense, the cost of drugs is also a major household expenditure. Given the substantial size of the private and public drug expenditure in all countries, it is no surprise that pharmaceutical expenditure can be wasted as a result of corruption at various points throughout the pharmaceutical system. In Albania private expenditure for health is 56% of total expenditure on health, all of which is out of pocket given there is no private health insurance in country. Government expenditure on health represents 10% of the national budget and nearly 7% of GDP.[1] Thus finding ways to ensure the most cost efficient, safe and efficacious drug supply is a primary goal in health system reform and modernization.

The World Health Organization (WHO) has long recognized that the pharmaceutical sector is particularly vulnerable to corruption which can take many forms. Forms can include bribery, fraud, favoritism, collusion, and embezzlement at all levels of the pharmaceutical supply chain and be as severe as criminal activity or not criminal but simply procedures that are broken and do not support the national goal of access to medicines that are safe, efficacious, with good quality at affordable prices.

The World Bank has identified corruption as the single greatest obstacle to social and economic development. Its health specialists and numerous experts from around the world including the WHO consulted on the development of a methodology to measure transparency to improve good governance in the pharmaceutical sector. This methodology has been applied in Costa Rica and five other countries and has been adapted as a WHO analytical tool, hereafter referred to as the "tool". [i]

 The operation of all pharmaceutical systems can be understood from five main activities around which the tool is designed. These are drug selection, registration, inspection, promotion and procurement. Key study findings and recommendations are presented in this Executive Summary. The main body of the report details the operation of the pharmaceutical system in Albania and the five key activities plus that of pricing and finance. Finance is not part of the formal study tool, however because the pricing function and finance of drugs is essential to the drug supply it is included.

The tool has two components. It has questionnaires that are scored two ways. One is quantitative and these are the scores reported. The tool also collects qualitative data such as whether informants perceive corruption in the sector. This part of the study also

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[i] *Measuring Transparency to improve good governance in the public pharmaceutical Sector*, Assessment Instrument, Working Document for field testing and revision, January 2007 (Rev. 1), WHO Departments of Medicines Policy and Standards (PSM) & Ethics, Trade, Human Rights and Health Law.

develops information on the system and its parts. This aspect of the tool is very informative and specific to Albania and fully describes where the points of vulnerability to corruption lie within the Albanian system.

DRUG REGULATION
SELECTION, REGISTRATION, INSPECTION, PROMOTION

DRUG SELECTION

SELECTION SCORE 3.6-- VERY VULNERABLE

The score on Drug Selection is the lowest of all five indicators in the tool. Since selection occurs in several activities of the pharmaceutical system this is a significant finding. The score is the result of the failure to have a national essential medicines list (EML) which means that decisions on what to procure and what to reimburse are vulnerable to corruption. An EML would provide an evidenced based framework to guide selection decisions. When asked about the EML, informant mentioned the Health Insurance Institute Reimbursement list as if it were the same, however it is not.

Albania has several committees and commissions within the Ministry of Health. They all suffer from the same weaknesses which include too few criteria for the appointment of members and too few or no criteria for their decision making process. The commission that makes selections of drugs to be reimbursed by health insurance, the Drug Commission on Drafting and Reviewing the Reimbursement List (DC), lacks standard operating guidelines on decision making and there are few if any criteria for the appointment of its members. There is no conflict of interest provision specific to this commission's work or that of any other part of the pharmaceutical supply chain in Albania. Though the tool does not examine how the drugs are selected for procurement, it is likely the score would also be very low as a result of the lack of defined methods to develop a hospital needs list and the subsequent commodity list to be procured, and the failure to coordinate the hospital list with an EML. Accordingly, recommendations in this section apply to all points in the pharmaceutical system in which drug selection occurs, including selection for reimbursement list, national procurement, prescription practice by doctors, and hospital needs list preparation.

RECOMMENDATIONS

1. Assign responsibility within the Ministry of Health for the EML, update 1994 EML and continue to do so every two years.
2. Base all drug selection processes including drugs purchased by procurement and those that are reimbursed on an evidence based system related to the national EML and include cost benefit analysis.
3. Develop and apply medical protocols which specify prescription or OTC drugs.

4. Develop criteria for selection of members of all commissions that are relevant to the purpose of the commission and establish decision making guidelines for all commissions. Develop conflict of interest guidance on all aspects of the pharmaceutical supply chain.

DRUG REGISTRATION

REGISTRATION SCORE 7.2-- MARGINALLY VULNERABLE

Albania has a relatively modern law and regulation on drug registration which does fulfill a number of requirements considered essential to the reduction of vulnerability to corruption. Nonetheless, the tool identified and accordingly the score lowered due to certain issues not addressed by it and the manner in which it is applied. Another area of weakness is limited staff capacity due to inexperienced staff in registration, which suffers from frequent turnover as a result of political change and career choices. Numerous specific recommendations can be easily implemented in the registration area to address regulatory gaps. More problematical is the hiring and retention of experienced staff, a step which may require salary increases and on the job training.

Another commission, Komisioni I Nomenklatures se Barnave (KNB) is part of the drug registration process. This commission suffers from the same issues as all others - membership is not based on any specific guidelines and there are no criteria for decision making or COI provisions relevant to registration. This commission is intended to provide the clinical expertise otherwise not found in the National Center for Drug Control (QKKB), however its capacity is limited to the expertise of professionals in the country and it is not clear whether this can be addressed internally. Accordingly, member appointments and resulting decisions can give the appearance of potential for corruption. In the absence of clinically capable members, registration decisions may not be in the best interest of Albanians and a corrupt condition, not behavior.

There is no formal appeals system in place in registration or any other aspect of the pharmaceutical system. Applicants appeal to the Minister who has final decision making authority over the recommendations of the drug registration specialists and the KNB. Thus, there is opportunity for appellant to seek to influence the decision of the Minister on drug registration and in other appeals. A separate board or administrative system to hear and determine appeals should be implemented.

RECOMMENDATIONS

1. Revise system to provide technical and clinical review of drug applications.
   a. More requirements and requirements to be stated more clearly in the regulations.
   b. Shorten the process.
   c. Specify and clarify evaluation criteria and process.

2. Refine the advisory role now conducted by KNB to include more specific technical and clinical competence according to the specific drugs in application. [ii]
3. Provide for technical and clinical decisions to be implemented without further review.
4. Registration specialists need to be specialized and have more professional competence

DRUG INSPECTION

INSPECTION SCORE 4.84--MODERATELY VULNERABLE

This score only relates to inspections conducted pursuant to the drug law and done by the QKKB inspectors. The overall score was reduced due to the lack of good manufacturing prices (GMP) and good distribution practices (GDP) or other standards with which the inspectors could conduct inspections. Also the lack of standards for the selection of inspectors and lack of a system to avoid regulatory capture lowered the score.

This report describes inspection from four vantage points in the system in which an inspection of any kind is conducted. These: 1) in the QKKB inspection process; 2) in HII inspection of pharmacies; 3) of drugs procured; and 4) the lab testing done on drugs presented for registration.

RECOMMENDATIONS ON ALL FOUR ASPECTS OF INSPECTION

A. QKKB Inspections
1. Appoint technical staff based on technical ability.
2. Increase inspections at all parts of the system.
3. Inform/train inspectors on regulations, procedures, what is included in an inspection, standard operating procedures (SOP).
4. Improve recruitment process. Retain inspectors.
5. Terms of reference for inspectors.
6. COI guidelines for inspectors.
7. Inform companies that are inspected about inspection.
8. Better salary and training on the job.

B. HII Inspections
1. Continue these and improve systems for audit and accounting.

C. Procurement Inspections
1. Transfer the procurement inspection function to the QKKB inspection department with specific terms of reference.
2. Automate the procurement delivery confirmation process with a system such as bar coding and require all procurement bidders to bar code product packaging.

[ii] See USFDA Advisory Committees http://www.fda.gov/oc/advisory/default.htm as a model for how committees can be established, COI requirements and more.

3. Extend automated system to the hospital pharmacy and medical stores department and to the point where drugs are dispensed to patients.

D. Lab Testing
      1. Continue good lab testing. No change recommended.

DRUG PROMOTION

PROMOTION SCORE 6.5--MARGINALLY VULNERABLE

The score on promotion is 6.5 marginally vulnerable due to the lack of a SOP for pre-approving or monitoring drug promotion and advertising, and the weaknesses in the formal complaints procedure to report unethical conduct, which is not in the laws but in the Code of the Order of Pharmacists. The Order has little power to enforce the law and the Code.

RECOMMENDATIONS

1. Develop a set of regulations in conjunction with civil society to regulate drug promotion and to amplify the role and power of the Order of Pharmacists.
2. Integrate international standards and practices to the regulations and improve the drug law to reflect the increased powers and duties of the Order.
3. Increase the professional standards for physicians, nurses and pharmacists.

FINANCE AND THE PHARMACEUTICAL SYSTEM

REIMBURSEMENT SYSTEM ESTIMATED SCORE 2.0--VERY VULNERABLE

The tool does not provide a questionnaire for the reimbursement system nor the work of the Drug Pricing Commission (DPC). However, one can estimate what the score would be given the lack of selection criteria for DPC members and lack of SOPs to guide decision making. Also of great concern are reports of abusive and corrupt behavior at the pharmacy and prescriber/doctor levels. These kinds of abuses are a target of HII inspections which are really audits and should be strengthened.

RECOMMENDATIONS

Like many of the other recommendations in this report, the process of drug pricing should be subject to criteria for the selection of members of any commission to determine prices and SOPs for decision making. Also, audits of doctors and pharmacies should be enhanced with additional systems and contract enforcement.

PROCUREMENT

PROCUREMENT SCORE 6.6--MARGINALLY VULNERABLE

The score on procurement indicates vulnerability to corruption resulting from the lack of guidance to procurement office staff on decision making in regard to the type of procurement to conduct and lack of an objective quantification method to determine the quantity of drugs to procure. There is also no SOP for the routine inspection of consignments and no management information system to track drugs procured. The planning phase was reported to be the weakest in the system by informants and on this point this author concurs.   Informants thought the new procurement law greatly improved the system but that the pharmaceutical system could benefit from adjustments.

RECOMMENDATIONS

1. Pre-procurement:
   a. Develop quantification system at all hospitals with a requirement to match needs lists with national essential medicines list and medical treatment protocols.
   b. Develop method to verify drugs dispensed at hospital, the data of which is integrated with the quantification system.
   c. Develop method for quantification of procurement commodity list.
   d. Schedule tenders to correspond with consumption rate and draft contract language accordingly.

2. Post-procurement
   a. Develop and procure minimum formularies for all hospitals and maintain these as part of the regular procurement system.
   b. Require FuFarma to deliver accordingly and to respond to requests from hospitals for urgent needs.
   c. Develop emergency supply system.
   d. Track drugs from producer to patient. Install a pedigree requirement or other system to track who has possession of drugs from producer to patient.

3. Price Controls
   a. Develop system to confirm original producer pricing.
   b. Integrate pricing mechanisms throughout pharmaceutical system, including declared prices, procurement pricing, and HII pricing.

CONCLUSION

The Albanian Draft Health System Strategy has identified improving health system governance as one of the four strategic priorities for the period 2007-2013. Coordinating the recommendations of this study with other steps to realize this priority will enhance

the ability of the Ministry to accomplish the other three priorities and improve the ability to provide access to drugs of good quality, efficacy and safety at affordable prices. In particular, current efforts to revise the health, drug and health finance laws should take into account the recommendations of this report to ensure that a sufficient legal and regulatory framework is provided and can support proposed changes in SOPs and processes. In addition, it is critical that consultative processes and training are engaged at all levels with staff and civil society to ensure consensus, acceptance and adoption of changes to the pharmaceutical system.

A SUMMARY ON HOW THE WHO METHODOLOGY WAS
ADAPTED AND REFINED
FOR THE ALBANIAN CONTEXT

The main changes in the tool are as listed below. Given that the five main functions of the Albanian pharmaceutical system are managed by multiple departments, divisions and committees within the Ministry of Health, this tool does not capture with sufficient clarity the potential impact each has in terms of vulnerability to corruption. Accordingly the tool has been modified to reflect this weakness. The fully amended tool is attached at Appendix D and an overview of the amendments is summarized below.

The caveat is that these modifications are made in terms of the system as it exists in October 2007. If there are any changes to this system the tool will have to be modified to reflect these changes and maintain its specificity.

Summary of Amendments

1. The language in the tool has been simplified and the questions shortened.
2. The names of the various departments, commissions, institutes and arms of the MOH have been identified in the tool as the target for study.
3. It is recommended that the tool is applied as follows:
   a. Selection
      i. New EML body
      ii. HII Selection
      iii. Commodity list for procurement
   b. Registration
      i. QKKB Registration staff and Chief
      ii. KNB
      iii. Medical products registration process
   c. Inspection
      i. QKKB as applied to drug registration
      ii. HII Inspections
      iii. Procurement inspections
   d. Promotion
      i. Wholesalers, distributors
      ii. Doctors
      iii. Pharmacists
      iv. Pharmaceutical companies
   e. Procurement
      i. Quantification for procurement
      ii. Specification process in hospital level
      iii. Distribution and dispensing processes
   f. Create new tool on Drug Pricing

INTRODUCTION

WHY STUDY THE PHARMACEUTICAL SECTOR?

The World Health Organization (WHO) has long recognized that the pharmaceutical sector is particularly vulnerable to corruption which can take many forms. Forms can include bribery, fraud, favoritism, collusion, and embezzlement at all levels of the pharmaceutical supply chain. They can be as severe as criminal activity or not criminal at all but simply procedures that are broken and do not support the national goal of access to medicines that are safe, efficacious, with good quality at affordable prices.

The World Bank has identified corruption as the single greatest obstacle to social and economic development. Its health specialists and numerous experts from around the world including the WHO consulted on the development of a methodology to measure transparency to improve good governance in the pharmaceutical sector. This methodology has been applied in Costa Rica and five other countries and has been adapted as a WHO analytical tool, hereafter referred to as the "tool". [iii]

No health system can function without pharmaceuticals the cost of which represents a major portion of public health expenditure in all countries. In developing countries where most of the cost is borne by patients as out of pocket expense, the cost of drugs is also a major household expenditure. Given the substantial size of the private and public drug expenditure in all countries, it is no surprise that pharmaceutical expenditure can be wasted as a result of corruption at various points throughout the pharmaceutical system. In Albania private expenditure for health is 56% of total expenditure on health, all of which is out of pocket given there is no private health insurance in country. Government expenditure on health represents 10% of the national budget and nearly 7% of GDP.[2] Thus finding ways to ensure the most cost efficient, safe and efficacious drug supply is a primary goal in health system reform and modernization.

Current health reform practice recommends a three step process to address corruption in the pharmaceutical system. The first is to assess the national system, which is why this study was commissioned. The second step is to establish a consultative process to develop and implement national frameworks to promote good governance in the sector. The third step is to train all involved in the sector on the new framework. It is not the goal of this study to investigate or prosecute any individual or group for corruption. Rather the goal is to assess the risks of corruption, the resulting waste and the reduced ability to provide safe and effective medications in Albania's pharmaceutical system, and to provide policy recommendations in response.

[iii] *Measuring Transparency to improve good governance in the public pharmaceutical Sector*, Assessment Instrument, Working Document for field testing and revision, January 2007 (Rev. 1), WHO Departments of Medicines Policy and Standards (PSM) & Ethics, Trade, Human Rights and Health Law.

In addition to the first step of assessment, the assessment tool is to be adapted for the Albania context so that at a later time a subsequent study can be conducted and results compared. A presentation of the results is anticipated and training will be conducted locally on how to apply the tool.

THE CONDUCT OF THE STUDY

Commencing in June 2007 and continuing to November 2007, the tool was applied in Albania. The tool is composed of questionnaires, each of which represents one of the five key components of all pharmaceutical systems, including drug registration, promotion, inspections, selection and procurement. A total of 39 informants responded to the questionnaires individually, and three focus groups and more than ten interviews were conducted for qualitative data and to supplement information developed by the questionnaires and desk top research.

The focus of this study was on national level activities in the pharmaceutical system and those of Mother Teresa Hospital (TUHA). No analysis was conducted at regional or local levels. Desk research was also conducted and those resources are listed at Appendix B. Appendix C lists the types of informants interviewed. The names of all informants will be maintained confidentially by the consultant as will the original notes from the questionnaires. The manner of scoring the questionnaires is determined by the tool, a copy of which has been made available to the Ministry of Health and is also available on the internet, the link to which can be found in the bibliography at Appendix B. The rating scale used to score the vulnerability to corruption is included in Appendix A. A summary of the raw data are attached as Appendix D.

TABLE A	REGISTRATION	PROMOTION	INSPECTIONS	SELECTION	PROCUREMENT	TOTAL
Informants	7	8	5*	11	8	39
Questionnaire	5	3	2	4	5	19

Table A: Informant Interviews by Category and Number of Informants

* Same persons as in registration total so this number is not included in total.

PRIOR STUDIES ON CORRUPTION IN ALBANIA

Several studies on corruption in Albania have been conducted in recent years, although none on its pharmaceutical sector. The Global Corruption Report for 2006 by Transparency International was devoted to corruption in the health sector, although Albania was not reviewed.[iv] This report provides some important overall guidance on corruption in the health sector including the perspectives of the pharmaceutical and health services sectors.

Some relevant work has been done on Albania by T. Vian, et al on informal payments in the health sector.[3] This work demonstrates that the majority of Albanian citizens make under the table payments for health care services even though in theory,

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[iv] Transparency International – www.transparency.org.

providers are paid by the government. In transition countries such as Albania, informal payments are viewed as an important source of health financing. This is so in particularly in countries in which health care is publicly financed and delivered. If also characterized by minimal funding and limited accountability, publicly delivered care falls prey to illegal payments. Such abuses can be addressed with improved oversight, accountability for public health care providers, and a role for patients to hold providers accountable.[4] Corruption in the provision of services in the public sector is an indicator of corruption in other aspects of the health sector, most notably in the pharmaceutical system.

DEFINING CORRUPTION

The word corruption can mean several types of behaviors and conditions. Behaviors can include bribery, fraud, favoritism, and embezzlement which are essentially criminal in nature and considered so under the law of most countries including Albania. Conditions are a failure in the system because of procedures that do not exist, or if they do they are too weak to provide guidance to those involved in the process. When low moral standards or no moral standards characterize the situation and weak procedures are in place, the system can be vulnerable to corruption.

Another aspect of corrupt behavior can include reference to public officials as is found in the most globally accepted technical meaning of the word as evidenced by Organization for Economic and Development Cooperation (OECD) anti-corruption conventions in force today. In this sense corruption means:

> "to offer, promise or give any undue pecuniary or other advantage, whether directly or through intermediaries, to a pubic official, for that official or for a third party, in order that the official act or refrain from acting in relation to the performance of official duties, in order to obtain or retain business or other improper advantage in the conduct of international business."[v]

Any acts which fulfill this definition are clearly corruption and such behavior should be prohibited and prosecuted. However, while this study identifies opportunities where corruption fulfilling this definition can arise in Albania, it is important to keep in mind that other behavior can be as damaging if not more so to the overall functioning of the pharmaceutical system. These behaviors can include illegal acts such as theft and document forgery or falsification, and poor procedures that result in poor management of all aspects of the pharmaceutical system.

This report will show the pharmaceutical system is vulnerable to corruption and that this is the result of criminal acts and poor or non-existing processes.   Clearly, direct acts of corruption should be prosecuted, however the identification and prosecution of persons engaged in actual corrupt behavior may not yield as much benefit to the overall system as addressing procedural and governance issues will. In the end the prosecution of a few criminals will not improve the system unless in the end the system is improved.

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[v] OAC Convention on Bribing.

AN OVERVIEW OF THE STRUCTURE OF ALBANIA'S HEALTH SECTOR AND PHARMACEUTICAL SYSTEM

Health care in Albania is predominantly publicly funded and delivered, though there is a growing private medical practice sector not covered in this study. The sector is managed by the Albanian Ministry of Health (MOH), the main functions of which include regulation, planning, finance and the provision of services. Private sector pharmacies and suppliers, including wholesalers, importers, manufacturers and distributors are also part of the health system.

The pharmaceutical system is best understood as it is integrated with publicly funded hospital and outpatient clinical health care services. It is a bifurcated system with two branches: 1) public sector procurement for the supply of pharmaceuticals, medical consumables and equipment to public hospitals and clinics; and 2) the private sector procurement of drugs for outpatient use which are financed through a national insurance scheme managed by the Health Insurance Institute (HII).

Albania spends about 7% of GDP on health, with some 44% of total health expenditures publicly financed and the balance from private expenditure. Total spending on health is €112 per capita in Albania compared with neighboring Eastern European and Central Asian countries of € 170per capita.[vi] The overall drug budget for Albania is estimated by the Finance Department to be € 80-90 million, plus out of pocket expenditure. That number represents about €50 million for public sector procurement and €40 million for reimbursement of outpatient purchases through HII. It is estimated that the MOH finances only 90% or less of the drugs necessary for Albanian health. A private sector estimate indicates the total Albanian drug market at €100 million, suggesting that out of pocket expenditures are about €10million per year. With an estimated population of 3 million persons, these budget estimates suggest per capita spending on drugs to be approximately €30 per person.

The list of drugs registered in Albania according to the National Center for Drug Control (QKKB) contains a bit over 3000 products, of which about 1390 have distinct International Non-proprietary Names (INN). Compared to neighboring countries, this number of registered drugs is high. In Bosnia Herzegovina the number of registered drugs is 1630, of which 913 have distinct INN; in Macedonia 1200 registered drugs, of which 750 have distinct INN; and in Yugoslavia 1200 registered drugs, of which 60 have distinct INN.

Most drugs are imported into Albania, are from many countries of origin or place of production, but appear to be imported only by Albanian importers of which there are many. Nine multinationals number with producers from the EU, Balkans, India, China, and Turkey among others with products registered in Albania. There are three local

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[vi] 2004 World Bank HNP data.

private manufacturers, ProFarma, Euromedica and RadoFarma, one of which is rumored to be owned by a Member of Parliament.

The HII reimbursement list is estimated to contain 220 drugs with separate INNs, and a total of 824 items including differing doses and formulations. By volume the sources of drugs on the HII list are estimated to be 20% from Albania, 43% EU, 30% Balkan, and the 7% balance from India, China and Turkey. By value, EU holds 65% of the market, India 11%, the Balkans and Albania 7% each. Customs data for the first half of 2007 confirm these estimates relative to all imports. No similar statistics are available from the QKKB regarding the list of registered drugs, but it is likely that a similar result would be found.

THE STRUCTURE OF THIS REPORT

The operation of all pharmaceutical systems can be understood from five main activities around which the tool is designed. The Albanian pharmaceutical sector contains all five activities of drug registration, procurement, promotion, selection, and inspection. These are either administered or affected by the MOH through its departments, committees or arms, or combination of one or more. In the case of promotion, a parastatal organ is also involved and in the case of procurement, private suppliers participate.

Study findings in this report are presented by grouping under regulation the activities of selection, registration, promotion, and inspection, followed by the role of finance in the pharmaceutical sector and finally procurement. Chart A- D are organization charts of these main activities and the departments or separate arms of the central MOH that conducts related activities as they exist as of November 2007.

DRUG REGULATION
SELECTION, REGISTRATION, INSPECTION, PROMOTION

DRUG SELECTION

IN GENERAL

The activity of drug selection is conducted in Albania through four different bodies or activities. These are drug selection for the HII reimbursement list conducted by the DC, by the approval process for drug registration conducted by the Komisioni I Nomenklatures se Barnave (KNB), by the drugs identified for procurement through national procurement and finally drug pricing by the DPC. The main focus of the tool is selection based on a national essential medicines list as the guiding framework for all selection. The four activities of selection are not directly assessed by the tool; however they are described in this report from a qualitative perspective as they all affect selection and demonstrate points of vulnerability to corruption.

An Albanian national essential medicines list was established in 1995 with assistance from the WHO, although no one could produce a copy of this list. It has never been updated since. It does appear that the KNB may have a role in the determination of this list, although in practice it does not perform this function. When asked about drug selection, most informants responded by describing the HII reimbursement list and the DC. There is no other selection function at the MOH. No other function or activity determines what drugs should or can be registered for sale within Albania, or in use at hospitals and while the reimbursement list is a form of selection it is not a national essential medicines list in its technical sense.

> *What is an essential medicines list and why does a country need one?*
> **Description:** An essential medicines list is a published document that identifies those drugs determined by a national authority to be essential for key public health problems in a country and that should be available through the public health system. It is a drug selection tool that, if prepared well, can help governments purchase appropriate drugs for their population.
>
> **Rationale:** An essential medicines list, if used properly, can help to ensure that drug expenditure is not wasted by the government on unnecessary drug products that may be promoted by suppliers to governments through the use of legal marketing strategies or illegal payoffs.
> <div align="right">Tool Section IV Drug Selection</div>

The work of the DC, KNB and DPC and on the HII reimbursement list is not guided by an EML, yet these committees do have a selection role and are discussed below. In addition, there are no national medical treatment protocols or evidence based decision making to guide best practice in the use of drugs within the four processes. No SOP is available for membership selection or decision making.

DRUG SELECTION FOR REIMBURSEMENT BY HII

A form of drug selection is conducted by the development of the list of drugs that are reimbursed by the HII. DC members are selected by its chair, the Minister of Health, and include the head of HII, and representatives from the Institute of Health, National Center on Drugs and directors of the hospital services at the TUHA. There are no criteria for the selection of members beyond the group of MOH bodies from which they are to be selected. There is no requirement for a pharmacologist or pharmacist on the DC; however a member from the wholesalers association is a permitted member. In practice any person has the right to propose a drug to the HII list and the hospital and clinical services present suggestions to their directors for what should be on this list for products used in ambulatory or outpatient care.

DC members are subject to the national conflict of interest law in which there are no provisions specific to the pharmaceutical system. Neither the Minister nor the head of HII were interviewed on the DC although interview requests were made. The list in its final formulation is not the result of any systematic methodology. Nor is it determined according to any SOP, or a national essential medicines list.

DRUG SELECTION IN THE PROCUREMENT PROCESS

Albania procures drugs and medical supplies for its hospitals and clinics. The overall procurement process is described later in this report. Here, the segment of the procurement process that identifies or selects which drugs to purchase through the tender process is considered.

Prior to the annual procurement period in Albania, hospitals prepare a needs list. No one could provide much detail on the process by which the needs list of each hospital is prepared, except to indicate it is negotiated with the professors and heads of the services at TUHA and all other 42 hospitals in the country. At no level does it appear that the list each hospital prepares is guided by any systematic method to match drugs selected to the disease profile of the district nor the prevalence and incidence of disease. Hospitals in effect prepare their needs lists based on physician prescribing practices, which are not guided by national treatment protocols, so this aspect of decision making is vulnerable to corruption and certainly promotional practices. Each hospital then presents its list to the Hospital Department at the central MOH. It seems that since July 2007 when this study was commenced there has been a change in this process which now directs this list to be presented to the MOH Planning Department which has been separated from the Hospital Department. No interview was held with the director of the Planning Department even though one was requested.

In either case, it is clear that the Hospital/Planning department aggregates hospital needs and determines the types of drugs, formulations and quantities to be procured taking into consideration the current budget. No informant reported that any objective methodology, such as scientific evidence or medical protocols, or quantification method is used to conduct drug selection at any level of the procurement system. Moreover, under the current practice, all quantifications of drugs are suspect as there is no means to systematically record what is dispensed to patients in hospital and actually consumed. Thus the rough estimate of needs prepared by hospitals adjusted pre- procurement by the Planning Department explains the number of items either over or under supplied in hospital. Given that nearly 50% of the national budget for drugs is expended in national procurement, this aspect of drug selection is ripe for abuse and in need of immediate attention.

There is also no system in place to sequence delivery or order the supply of drugs to correspond with the consumption rate in hospital. Short supplies or stock outs occur in Albania and can be partially if not fully explained because either no product was ordered and/or the rate of dispensing exceeds the delivery rate. If an emergency were to occur the system disrupted more. There is also no basic minimum hospital formulary either in terms of type of drug or quantity to be maintained as a basic minimum inventory. No matter how well run a system is, shortages can and do occur, thus a minimum formulary will provide a cushion. A hospital interview revealed there was no saline in stock in Mother Theresa hospital, thus no IVs could be hung. More disturbing is that the hospital pharmacy knew which distributor was responsible to deliver saline and called, only to be told delivery would occur but not necessarily in time for the hospital to be spared a stock out. This scenario should be frightening to any and all Albanians, but can be easily remedied with the development of a quantification system, a minimum basic hospital formulary, its purchase and maintenance.

> *Is procurement done with an objective quantification method to determine the quantity of pharmaceuticals to be purchased?*
> **Rationale:** To reduce the risk of over-supply, under-supply, or unnecessary supply of pharmaceuticals, drug purchases should be based on objective, actual or expected health needs, and on budget availability. Use of an established methodology for estimating needs reduces vulnerability to unwarranted pressure from pharmaceutical suppliers to make drug purchases by government officials through the use of kickbacks and other types of payoffs.
> **Description:** There are four major methods for quantifying drug needs: consumption (based on historical data), morbidity-based, adjusted consumption, and service-level projection. Ideally, a combination of these will be applied to obtain the most accurate estimates.
>
> Tool Section IV Drug Procurement

SELECTION SCORE 3.6--VERY VULNERABLE

The score on Drug Selection is the lowest of all five indicators in the tool. From a quantitative perspective drug selection is Very Vulnerable according to the tool, the entire scale of which is presented in Appendix A. The specific scores on each question in the tool can be reviewed in the Appendix D. The failure to have a national EML, the lack of guidelines for selection of members of the DC and lack of any standard operating guidelines and rules on decision making for the DC on drug selection for the HII reimbursement list were the main components of the low score. While the tool questionnaire on procurement does not examine how the drugs are selected for procurement, it is likely the score would be also low indicating the high vulnerability to corruption in this area.

RECOMMENDATIONS

1. Assign responsibility to update EML, update 1994 EML and continue to do so every two years.
   a. Base all national drug selection for procurement and reimbursement on an evidence based system related to the national EML, to include cost benefit analysis.
   b. Develop policies and procedures to require all drug selection activities to reflect the national EML including registration approval, procurement and reimbursement.
   c. Revise or abolish the Drug Commission. It is unnecessary if appropriate evidence based methods are used to select and quantify drugs for reimbursement and procurement.

2. Develop and apply medical treatment protocols.
   a. Specify prescription or OTC drugs in protocols.
   b. Require physicians to comply with treatment protocols in hospital and in prescribing from the HII reimbursement list.
   c. Train prescribers on the use of the list of registered drugs, the use of generic versus branded products, so lower cost generics are prescribed by doctors in hospital and for outpatient use.

3. Select quantification method to determine the hospital needs list, indicating the types and amounts of drugs to be purchased within the procurement budget and select a method to harmonize the needs list with the budget so as to avoid arbitrary decisions on what should be procured.
   a. Provide to and require hospitals to use a common quantification system to determine what type and quantity of drugs are consumed and necessary to have in supply in Albania.
   b. Establish for each hospital a minimum formulary in terms of type, dose, formulation and quantity for a certain period. Procure this and maintain a minimum quantity on hand.

c. Train on medical supply inventory maintenance and storage. Put pharmacists in hospitals and pay them an adequate salary so they remain in their jobs.

4. Establish a COI policy on drug selection and enforce.

DRUG REGISTRATION

IN GENERAL

The QKKB is responsible for drug registration, inspection and the regulation of promotion. The former director of the center was interviewed however the new director was not available for interview. The Chief of Registration who has held the post only a short time abruptly ended the interview and did not reschedule for completion. Interviews were also conducted with the Chief of Inspection and the Information section which provided input on the regulation of promotion.

The QKKB has a web site that does contain the law, regulations and forms to be used to register drugs; however these are only in Albanian. The regulations can be obtained in published form in English however no one at QKKB not at MOH or HII was able to provide a copy of the drug legislation in English. It appears work is being done to revise the national drug legislation to conform to requirements of EU integration.

The process of registering a drug begins with the filing of an application, review by the Registration Chief and one of the five registration specialists who determine whether the documents are sufficient and have the authority to require testing by the QKKB Laboratory. After review by the registration unit, the files are sent to the KNB. Once the KNB completes its review, its recommendation along with that of the QKKB registration unit are sent to the Minister for final approval and the issuance of a registration or marketing approval for the Albanian market. Overall this process takes about six to nine or more months for completion.

Any product can be registered in Albania by any entity. Registration is not limited to the original manufacturer or patent or trademark holder. It was reported that there is a prohibition that if the active pharmaceutical ingredient of a drug is registered no other trademarked version can be registered. No confirmation of this statement could be found, however if true then the list of registered drugs will be limited to the first to file and reduce competition. It was estimated 3500 products a year are registered. In comparison US generic drug applications numbered 307 in FY 2002 and increased to 793 in FY 2006. Thus the number of applications per year is substantial, though this may reflect a catch up period for Albania which was closed to outside markets for a long part of its history.

The list of registered drugs which is on the QKKB web site indicates some 3000 drugs are registered and for which registration is current. According to informants this list

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is current, although it is not clear whether practitioners know about this list to understand what products could be available in the country for prescription to patients in the hospital or on an out patient basis.

The fee to register a drug is €800 for a prescription drug, € 300 for food supplements and € 800 for herbal medicines. The KNB is in theory responsible to make a determination of what is a prescription drug, an OTC, an herbal product or food supplement and these determinations set the fee which is paid prior to registration. Another department in the MOH registers medical devices such as syringes, equipment and test kits. This work of this other department is not covered by this study, but should be as the expenditure on non-drug medical products is also a large part of any health budget.

If a drug is already approved by the European Agency for Drugs Control (EMEA), the time period the QKKB can review the dossier is reduced from 6 to 2 months according to the regulations. It is reported that no laboratory analysis is done on EMEA products however all others are analyzed in the laboratory at QKKB.

While not specifically relevant to registration, it is notable the QKKB also issues import approvals to holders of marketing authorization. Even though marketing approval is granted, a holder must still get a separate authorization each time it brings a shipment of drugs into Albania. The rationale for this step is unclear especially since an importer must also present import documents at the port of entry and there is an inspection of procured products, for a possible total of three approvals on imports. Once documentation is presented including certificate of analysis, invoices, and certification of authority by the marketing authorization holder, the QKKB issues stamps, which it prints for each box to be imported which the importer must attach. The stamps indicate the import permission number, a batch release number and price for the product.

As mentioned above, the KNB is involved in drug registration and functions as an advisory body to provide technical and clinical input. Members are selected by the Minister of Health and serve for an indeterminate time period. No one was able to indicate how members are selected except to say they are "specialists". There does not appear to be any grouping of drug application by therapeutic category nor selection of members with specialties relevant to the drugs to be reviewed. Members are compensated approximately $500 Euros per year and meet about six times a year.

One former member of the KNB was able to provide a rough translation of Regulation Nr. 525, dated 1998, based on the 1994 Law on Drugs #7815. A request was made to the general counsel of the MOH for a copy or more formal translation and understanding of whether this is the entire regulation related to the KNB. No response has been received. Nonetheless, this regulation may be a key to the formation of the essential medicines list. The following points were mentioned in the regulation:

1. KNB members are subject to a one year appointment.
2. Members are paid.

3. Specialists in the relevant field are required, but the informant indicated this does not happen.
4. KNB is to provide a written report annually.
5. Complaints by applicants are to be sent to the Minister.
6. The KNB is to develop a national essential medicines list and provide technical capacity to the drug registration process by evaluating drugs.
7. KNB approves clinical trials with the MOH Ethical Committee according to the WHO Good Clinical Practice Guidelines.
8. The regulation indicates who is to serve on the DC to include representatives from KNB, QKKB, TUHA, HII, and the Director of Pharmaceutical Department at MOH.

The KNB must work within the time frame of the drug regulations which is 6 months. If the registration specialists do not send the files to the KNB with sufficient time to review within the time period this is a problem for them. In contrast, the US FDA acts on 55 percent of generic drug applications within 180 days as of 2007.

According to an informant the original intent of the KNB was to provide clinical and technical expertise to the process of drug registration because there were not enough clinical or technical experts at QKKB within the registration department. It was reported that no registration specialist has more than a year or two of experience past pharmacy school and generally none remain in the post for more than a year or so. It was also reported that registration department staff have all been changed by the new Minister in June 2007. Thus there is little to no professional development, nor institutional memory. Moreover, interviews suggested that even KNB members may not have sufficient technical expertise to review drugs and in particular new molecules. Coupled with a lack of guidelines on how the KNB should make decisions on drug application, any registration decision is open to question.

It is not uncommon practice to have an advisory committee of experts to supplement the expertise of regulatory agencies. Thus the use of an advisory body like KNB in and of itself is not a point of vulnerability for corruption. However these often have specific expertise relative to the drugs being registered. So for example if anti-cancer drugs are in the registration process and there is a need for special expertise, the cancer drug advisory committee would be convened rather than an overall committee that is selected without consideration of the therapeutic classes of the drug applications to be considered.

REGISTRATION SCORE 7.2--MARGINALLY VULNERABLE

The overall drug registration process is relatively transparent, although its weak points are significant. Its requirements and process are published, there is a list of registered drugs and some guidance to assessors on how to assess applications though this aspect of the review is somewhat ministerial resulting in the need for the KNB. For all staff and the KNB members, the COI law is not specific to drug registration. There is no formal appeals system in place, rather applicants appeal to the Minister. Thus, there is

opportunity for applicants to attempt to influence the decision of the Minister on drug registrations.

The selection of members of the KNB is not based on any specific guidelines relevant to the drugs being registered. The requirement of "specialist in the field" is not clear as to whether KNB members should be in pharmacology, pharmacy or in the diseases for which the drugs in application are used in treatment.

The score on drug registration while at the higher end of the scale should not be reason for comfort as informants report unethical behaviors of bribes, favoritism, and commercial interests in the companies of applicants as having an influence on what is registered. Informants also thought that benefits to officials in charge of registration have an influence on final decisions. In conclusion, informants believed both behavioral corruption and corrupt conditions in the form of poor processes exist.

RECOMMENDATIONS

A. Professional Standards;

1. Revise system to provide technical and clinical review of drug applications. Provide for technical and clinical decisions to be implemented as final. Specify and clarify evaluation criteria and process and establish reference to EML.
   a. Requirements for;
      1. API, excipient, and other content quality,
      2. Primary packaging – should be in Albanian and English
      3. Longer expiry period
      4. Bio-equivalence
      5. Clinical trials and cost benefit studies information
      6. Toxicity trials in Albania.
   b. Shorten the process. It takes too long – runs to nine months compared to EU average of 210 days. US goal - 180 days.
   c. Limit the number of drugs registered, for example do not need so many forms of paracetamol. Having so many on the list makes control difficult. Too many with the same name.
   d. Consider *fast track registration* for drugs approved by stringent regulatory authorities such as EMEA, Japan, US and Switzerland and those pre-qualified by the WHO.

2. Increase professional competence and specialization for registration staff and physicians.
   a. Increase salary
   b. Provide training and standards for performance.
   c. Proscribe meetings between applicants and specialist or chief of registration.

3. Refine the advisory role now conducted by KNB to include more specific technical and clinical competence according to the specific drugs in application. [vii] Include experts from outside TUHA so that appropriate experts can be consulted on products from all therapeutic classes and in particular new molecules. Require a pharmacologist and pharmacist to be on KNB. Increase Transparency of decision making

   a. Publish reports of the actions of the QKKB and KNB on the internet in English and Albanian.
   b. Provide drug legislation, regulations and applications on the internet in English.
   c. Publish the list of OTC drugs on the web site too- do not limit to prescription drugs.
   d. Establish pharmacovigilance process. Information department should announce and inform the public when reports are filed and doctors should register complaints with QKKB.
   e. Train physicians on the brand and generic names of drugs and how to prescribe by referencing the list of registered drugs.

B. Establish an appeal process and body separate from the Minister under a set of administrative regulations.

C. Add COI rules specific to registration.

D. Revise import approval process.

DRUG INSPECTION

IN GENERAL

Inspection occurs in four ways in Albania, the most formal of which are the inspections conducted according to the drug law by QKKB inspectors. In addition, HII conducts what it refers to as inspection of pharmacy contracts, a testing phase is conducted as part of the registration process, and finally a committee inspects drugs delivered to FuFarma as part of the procurement process. All four are described here, though the tool only considers QKKB inspections.

QKKB INSPECTIONS

There is an Inspection Department, Chief and staff of inspectors based both in Tirana and out station in about eight areas of the country. There do not appear to be any regulations on inspection according to the Director. The drug law grants power for inspectors to enter at any time or place where medicines are produced, packaged, stored or distributed or tested, and defines the duty to inspect. However, there are no national or

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[vii] See USFDA Advisory Committees http://www.fda.gov/oc/advisory/default.htm as a model for how committees can be established, COI requirements and more.

international references to standards for good manufacturing practices (GMP), or good distribution practices GDP or other standards relevant to the drug supply chain in the law. The Chief reported inspectors are not guided by standards that are clear and transparent so they can also be complied with by those who are inspected.

QKKB inspections are conducted on every imported drug to ensure that import stamps are in place and of the batch number, expiry date, and transport and distribution conditions. Inspections also occur at all ports of entry to Albania, at the three manufacturing facilities, and in distribution and storage depots.

There are no mechanisms to prevent regulatory capture or a situation in which the inspectors who are supposed to be acting in the public interest are dominated by the industry it oversees. As in other aspects of the pharmaceutical system, the COI laws are not specific to drug inspection, however, the new Chief of Inspection recently fired an inspector located outside Tirana for taking money and for not showing up to work on a regular basis.

Like other staff at QKKB, the only requirement for hiring is to be trained in pharmacy. Most inspectors have only a year or so experience in the work place, not necessarily as inspectors and most do not stay more than a year. The current director has worked in registration and HII in reimbursement but has no experience in inspections.

DRUG INSPECTION BY HII

A form of inspection is conducted by HII of those pharmacies with which it has a contract. In effect, this is an audit to examine the beginning and year end inventory to verify whether a pharmacy has met or exceeded its contract limits. This form of audit/inspection is very useful in ensuring compliance with contract limits, gathering consumption data and should be encouraged. Audit procedures can be considered for improvements in it sensitivity to corruption.

INSPECTION AS IT RELATES TO THE LABORATORY TESTING PHASE OF DRUG REGISTRATION

The inspection phase of drug registration is not the subject of a questionnaire in the tool. The QKKB laboratory tests non-EMEA drugs in the registration process, samples from inspections of manufacturers and randomized selections from the private sector, customs, and where there are any doubts about product. The lab is regarded as good according to staff. It was established more than 25 years ago according to WHO standards. There does not appear to be much prospect for corruption in this area as it is based on WHO standards and scientific methods.

INSPECTION AS IT RELATES TO PROCUREMENT

A new system is in place to inspect drugs purchased by procurement upon delivery. This inspection is not conducted by QKKB inspectors, even though QKKB issues the import stamp and has the role of inspection. Prior to July 2007, no process was

in place to inspect the drugs purchased by procurement tender to determine if what is delivered is what was "ordered" by procurement tender. Now, each week a team composed of one FuFarma representative, one from the MOH and one from QKKB meet at FuFarma and inspect tendered drugs. They review documents and conduct inspection of the following documents in comparison to the physical boxes of product. However no lab testing of products is conducted.

> Import permit
> Import Stamps – has trade name, batch # and hospital price, quantity confirmed
> Certificate of Origin – from seller is acceptable
> Certificate of Analysis – from manufacturer

This inspection process is conducted manually after which a paper report is transferred to electronic media by a computer operator. No bar coding or other electronic warehouse/inventory management systems are used to ensure that all products ordered by procurement are actually received. It is unclear why the existing QKKB inspectors who already inspect imports at ports of entry for import stamps and other required documents (which are the same as those inspected by this team) do not conduct this inspection and simply correlate what is delivered to procurement contract terms. With regard to domestically produced drugs, QKKB inspectors could be employed to inspect upon delivery to FuFarma. There is no system in place to ensure that all procured drugs are ultimately delivered to hospitals.

This new step should be applauded because a major point of vulnerability in the overall pharmaceutical supply chain is the absence of a pedigree requirement or other system to trace drugs from origin to patient. Such a system would monitor and record all steps and persons in the supply chain from producer to patient, a process that would greatly improve the pharmaceutical system in Albania and reduce waste, loss, theft and potential for corruption.

INSPECTION SCORE 4.84--MODERATELY VULNERABLE

This score only relates to inspections conducted pursuant to the drug law and done by the QKKB inspectors. The overall score was reduced due to the lack of GMP and GDP or other standards with which the inspectors could conduct inspections. Also the lack of standards for the selection of inspectors and lack of a system to avoid regulatory capture lowered the score.

RECOMMENDATIONS

Generally conduct the survey on all four kinds of inspection.

A. QKKB Inspections

1. Professionalism
   a. Appoint technical staff based on technical ability.
   b. Inform/train inspectors on regulations, procedures, what is

included in an inspection, SOPs.
c. Improve recruitment process. Retain inspectors.
d. Terms of reference for inspectors.
e. Better salary and training on the job.
2. COI guidelines for inspectors.
3. Transparency on inspection – better inform companies about inspection.
4. Increase inspections at all parts of the system.
5. Adopt national GMP and GDP standards and other standards relevant to drugs.

B. HII Inspections - Continue these and improve systems for audit and accounting.

C. Procurement Inspections
1. Transfer the procurement inspection function to the QKKB inspection department with specific terms of reference.
2. Automate the procurement delivery confirmation process with a system such as bar coding and require all procurement bidders to bar code product packaging. Until installation of bar coding or other electronic system, improve audit process for checking deliveries and have this done by MOH audit department.
3. Extend this system to the hospital pharmacy and medical stores department and to the point where drugs are dispensed to patients.

D. Lab Testing – Continue good testing process.

DRUG PROMOTION

IN GENERAL

The area of drug promotion is the least developed in terms of law, regulation and practice in Albania. According to informants, Section 52 and 53 of the drug law No. 9323, 11.25.2004 promotion is allowed but only for OTC drugs and only to doctors. For prescription drugs, only literature and professional or scientific events are allowed. Non drugs such as vitamins cannot be advertised. An informant stated about drug promotion in Albania, "If there are no rules, how can they be disrespected?" Ads appear even in the butcher shop according to another informant. This summarizes the main problem with the activity of promotion; there is an insufficient regulatory framework.   Examples of reported regulatory gaps are when a doctor urges the selection of a drug for HII reimbursement and payments allegedly made to hospital chiefs of services to recommend certain drugs for the HII reimbursement list and the list of drugs to be purchased by government tender.

Ways in which companies do promote their drugs include:
1. trainings and meetings,

2. free samples,
3. personal contact – giving of calendars, wine,
4. collaboration with distributors to provide free drugs – for example, buy 10 get one free, and
5. sponsoring doctors to go out of Albania to conferences.

None of these in particular is illegal but could be the basis of undue influence in the absence of guidelines on when such behaviors become potentially corrupt.

There is also a framework for professional discipline. The QKKB approves promotions and ads, however it is the Order of Pharmacists, a parastatal agency that receives reports of violations of promotion rules and thus has the right to and role of enforcement. It has a code governing its members which is in Albanian. Its disciplinary committee takes action against any pharmacist or pharmacy that breaks the rules. According to the Order, there is room for improvement in their role and they are actively considering recommendations for changes. There are many good examples of frameworks such as the one adopted in the EMEA.

There is an Order of Physicians which was not interviewed to determine what if any professional conduct standards there are and means to enforce these. There is a COI law but it is not specific to drug promotion.

PROMOTION SCORE 6.5--MARGINALLY VULNERABLE

The score on promotion is 6.5 marginally vulnerable due to the lack of an SOP for pre-approving or monitoring drug promotion and advertising, and the weaknesses in the formal complaints procedure to report unethical conduct, which is not in the laws but in the Code of the Order of Pharmacists. The Order has little power to enforce the law and the Code.

RECOMMENDATIONS

1. Develop a set of regulations in conjunction with civil society and the Order of Pharmacists and Order of Physicians to regulate drug promotion and to amplify the role and power of the Order of Pharmacists.

2. Integrate international standards and practices to the regulations and improve the drug law to reflect the increased powers and duties of the Order.

3. Increase the professional standards for physicians and pharmacists.

FINANCE AND THE PHARMACEUTICAL SYSTEM

IN GENERAL

Recalling there are two branches of the pharmaceutical system, public procurement and the reimbursement for drugs, this section discusses public finance of drugs for out patient use managed by the HII formed in 1995. Discussion of the financing of drugs is essential to this study because of the size of the budget which is nearly 50% of the overall national expenditure according to the estimates provided, thus, activities around this expenditure are vulnerable to corruption as is always the case with large public expenditures. It is also important because the private sector is the major other actor in this aspect of the pharmaceutical supply chain. Private sector actors include the original drug producer, the importers, wholesalers, distributors, sales representatives, pharmacies, pharmacists and finally patients. Last, the HII reimbursement list with its prices serves as a price setting mechanism with an influence on prices paid in government procurement.

The law creating HII declares it to be autonomous; however it is intimately connected to the Ministry of Health. The Ministry, according to the law, is responsible for the establishment of the DPC which sets prices for the reimbursement list and the DC which determines which drugs are on the reimbursement list. The law further requires that only the lowest price drugs are to be reimbursed. Article 15 of the HII law is reproduced in full below.

Article 15 Size of Reimbursement

1) The size of reimbursement for prices of essential drugs shall be defined every year by the HII with approval of Council of Ministers.

   Two technical commissions named "The Commission of Designing and Reviewing of the Reimbursable Drugs List" and "Drug Pricing Commission" established by the Minister of Health, design the list of reimbursable drugs". Pharmaceutical wholesalers association has its own representative in this Commission. With a proposal by the Ministry of Health this list is approved by the Council of Ministers.

2) Where there are more alternative drugs applied in any one case, with the same effect, the HII shall reimburse the cost of the least expensive one. The more expensive ones may be provided only under conditions to be defined by the Administrative Council of the HII.

HII operates much like a health insurance organization. It contracts with clinical centers to provide health services and with pharmacies to provide prescription drugs to patients. The health centers which are currently all and only public enter contracts with doctors who work at the centers; although it is not clear why contracts are needed as

doctors are civil servants in the Albanian publicly delivered health care system. HII also contracts with pharmacies that sell drugs that are reimbursed and those that are not. For reimbursed drugs, pharmacies are required to collect certain forms from patients, to annually account, and to only charge certain prices to patients in the form of co-pay and upon submission of appropriate paperwork are reimbursed at stated rates.

PRICING SETTING

The Director of the Pharmaceutical Department chairs the DPC. Its members include two members from the MOH, one from the Ministry of Economy, two from the HII and one from the Wholesalers Association.   The DPC is responsible for setting prices for drugs on the HII reimbursement list and sets the margins to be paid to members of the supply chain including the wholesalers, importers, distributors and pharmacists. There does not appear to be any selection criteria for this commission or any guidelines on how it should make decisions. There does not appear to be any reference to international pricing guides readily available on the internet from reliable sources. [viii]

The system appears to proceed as follows. Marketing authorization holders declare prices for the next annual period on October 31 in sealed envelopes which are submitted to the MOH, and apparently to the office of the Minister. After review by the DPC, negotiations between it and the marketing authorization holders, a list of maximum cost, insurance and freight[ix] (CIF) prices on imports and ExW prices on locally produced drugs is finalized. This list of prices is approved by the Council of Ministers along with the list of drugs approved by the DC. These prices are then inserted into the annual HII reimbursement list. It is reported that margins approved by the DPC permit maximum mark ups of 12.5% for importers and wholesalers, 5.5% for distributors and 29% for pharmacists for most drugs. For special drugs other rates are approved and for sole source drugs or extremely expensive drugs exceptions are made. A study was done on the financial needs of the members of the supply chain which established these ranges of mark ups, although it is not clear when the study was done or under what conditions.

The result of these mark ups is potential price increases of up to approximately 50% on the CIF price of drugs. While this may in and of itself not be an issue, clearly if the CIF price is inflated, then all others in the supply chain benefit and the ultimate cost to HII and patients is increased. According to Albanian Customs, in fact, there are cases in which different prices are declared on the producer's export declaration than that declared on the importers declared price. This activity is not only a violation of Albanian Customs law, but likely a violation of the laws on reimbursement and conflict of interest. This aspect of the supply chain is not the subject of the tool; however, it is clearly a significant vulnerability to corruption in the form of illegal price fixing, falsification of documents and other breaches of the law, both criminal and civil. Addressing this area should be an urgent focus of attention.

[viii] Examples are the International Drug Price Indicator Guide published by Management Sciences for Health and Sources and Prices of Selected Medicines and Diagnostics for People Living with HIV/AIDS, both of which are available on-line. +

[ix] Incoterms 2000.

A significant question arises in terms of the use of the prices set by the DPC in terms of national procurement, importation and its relationship to prices declared on the registration of drugs. The procurement process requires the tender committee (TC) to award bidders that meet technical specifications and offer the lowest prices. It is not clear from interviews whether there is any reference by the TC to the annual prices companies declare and which are approved neither by the DPC nor to prices declared on the registration of drugs. No data appears available to compare these prices. There was also some indication during interviews that the TC "accepts" not only the price but the margins approved by the DPC without regard to whether these margins are relevant to procurement. Moreover, it also appears the TC does not refer to external international pricing guides to verify the prices bid on tenders.

Another question arises as to whether the prices declared on application for import permits and stamps are the same throughout the entire pharmaceutical system.

ESTIMATED FINANCE SCORE 2.0--VERY VULNERABLE

The tool does not provide a questionnaire for the drug pricing and thus not the work of the DPC. However, one can estimate what the score would be given the lack of DPC membership selection criteria, lack of SOPs including reference pricing to guide decision making, and the reports of abusive and corrupt behavior at the pharmacy and prescriber levels. For example, it is reported that some doctors provide receipts to some pharmacies for drugs but no drugs are delivered to the patient. Another situation occurs at the pharmacy level in which the pharmacy dispenses unregistered drugs and is reimbursed but then sells registered drugs to customers who pay completely out of pocket. If caught, a pharmacy or doctor can have its contract with HII cancelled and case referred to the prosecutor. These kinds of abuses are the subject of the HII inspections which are really audits and these should be strengthened.

RECOMMENDATIONS

1. Enforce the Customs and other laws and contractual obligations to prosecute illegal price fixing and document falsification.

2. Require reference to national EML in the Reimbursement list and reference to international pricing guidelines for setting prices in addition to the marketing holders' declaration.

3. Establish criteria for membership in commissions and for decision making and COI specific to these tasks.

4. Explore other price setting mechanisms to ensure lowest drugs are lowest prices when finally dispensed by pharmacies to patients.

5.　　　Collect data on drug pricing in procurement, reimbursement, import stamps and registration.

NATIONAL PUBLIC PROCUREMENT

IN GENERAL

The other branch of the pharmaceutical system is national public procurement which is governed by the National Procurement Law. The MOH Department of Procurement annually organizes procurement tenders for the drugs and other supplies necessary for the 42 hospitals and clinics located around the country and including the only tertiary hospital in the country, TUHA. There is also a trauma center operated by the Albanian Military in Tirana which obtains some small budget from the MOH. This center was not included in this study. The HII and some of the hospitals, have separate procurement activities, and hospitals can and do spend some portion of their budget on drug purchases. However, this report is limited to the central procurement function of the Ministry of Health.

Annually hospitals and clinics estimate their needs for pharmaceuticals and provide this assessment to the Hospital/Planning Department. [x] This process is reported to be done by hospital staff estimating the quantities consumed in the prior year, although no specific methodology or quantification system is employed. Coupled with the lack of accountability in the area of pharmaceutical dispensing from the hospital pharmacy to the service to the patient level, these estimates are at best rough. Worsening the outcome is that the entire hospital supply system is organized so that it consumes the entire quantity annually procured and includes no mechanism for a cushion or minimum supply level to avoid stock-out situations or provide drugs for emergency situations such as an epidemic.

Once the Hospital/Planning Department receives the estimations, it develops a list of products to be tendered and adjusts this list according to the budget for the year in question. It is unknown what if any methods the department uses to select what is on the commodity list. It is expected that it will not be possible to purchase all that is requested; however, there seems to be no information on how the list is scaled down except that it is limited by the budget. This is an area of great concern as it remains a vulnerability to corruption in the absence of appropriate methodology and guidelines for decision making. Moreover, if this list does not reflect the national essential medicines list there is opportunity to procure inappropriate drugs. The reporting of both over and under stock at

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[x] Changes have occurred in the Hospital department since June 2007. Historically, the Hospital Department planning section organized the commodity list the Procurement Department should purchase. It seems the sections of the MOH that conduct planning, management, finance and administration were separated from the Hospitals Department.   Also staff were moved to the Procurement Department and a new director appointed. The Planning Department Director was unavailable for interview thus this description of the process is based on the reports of other MOH staff.

hospital confirms the weaknesses of the quantification method and the process by which the commodity list is developed. The topic of drugs selected for procurement is so important it is covered here briefly and in the earlier section of this report on drug selection.

After the commodity list is prepared, the Department of Procurement organizes tenders to procure the products. Department staff prepares procurement documents and advertise the tenders. In 2007, there were 18 open tenders and 2 negotiated and 26 suppliers won the bids, representing the fact that more than one supplier can win one bid, each supplying a portion. Staff report, the total budget for tenders for drugs alone conducted by the office in 2007 was about $US14million.

According to the national procurement law, it is required that if a tender is in excess of US$1 million dollars, then international tender is required. The procurement department director determines what goes into each tender according to his interview. However, there has never been an international tender which would require translation into English, advertisement in international media and longer time limits. While it is true that only drugs registered in Albania can be offered in a tender, the current approach may be precluding the best international pricing especially since certain importers are repeatedly winning tender bids as reported during interviews. There is no other conclusion to draw but that this approach has an effect on competition and thus pricing whether or not corrupt behavior is occurring. If the market is opened to international companies they will make a determination on whether to register their products in Albania. The registration process will only be a short term delay to the benefits to the entire system to encourage competition in drug pricing.

In the process of procurement, bids are published in the national procurement register and also on the website of the National Procurement Office of Albania. Any company can bid on a tender; it need not be registered in the country, or have a local agent, however since all advertisement and documents are only in the Albanian language, the effect is to limit the number of bidders who will enter the market and to those with local staff or representation. A recently developed e-*procurement* system is now in use by Albania by which bidders can register and submit bids on line. However the MOH does not use this system, although the Department of Procurement is aware of it.

Once bids are submitted, staff review the documents for compliance with technical requirements after which the TC makes a final decision and selects the lowest bidder which has met technical requirements. The Minister selects members of the TC based on recommendations made by the Department of Procurement which asserts its recommendations are based on the nature of the products tendered. There appears to be no reason to have a TC since the procurement law requires awarding bids to the lowest bidder which meets the technical specification of the tender. There do not appear to be standards for selection of TC members or how a determination is made that bids meet technical requirements. There is no requirement to refer to external reference pricing or to the prices declared to the Ministry each year by companies as part of the process in setting prices for the HII reimbursement list. Informants expressed concerns that prices

were not necessarily the lowest possible and did not know if there is any relationship to prices set by the DCP. Thus the TC itself and the tender process appear vulnerable to corruption.

The delivery and distribution of drugs procured by tender is an important part of the pharmaceutical system although not covered by the tool. Some of the decision points with the most vulnerability can be found in the delivery and distribution segment of the government procurement supply chain. These points of vulnerabilities substantially affect the information on which procurement quantification is based and without doubt create opportunity for theft, loss and waste. The delivery and distribution segment of the supply chain is perhaps easiest to correct with basic inventory management and pedigree or track and trace systems which can be paper based, electronic with the use of bar coding and of course more sophisticated systems which can be used for many other inventory management purposes such as annual quantification, specification and forecasting.

Delivery: Procurement documents generally require that 100% of the quantity tendered is delivered at one time, yet there are some cases when a lesser percent is initially delivered. Informants observe that two delivery issues arise (1) when the drugs are delivered to hospital not all the drugs ordered needed are delivered at the same time, and (2) if necessary drugs are procured, their availability does not correspond with the time they are needed. In the discussion on quantification, the subject of the types of drugs has been covered. In this section, the timing of delivery is covered. Clearly the system does not stage deliveries to correspond to the consumption rates in hospital, even assuming this is known. Assuming the consumption rate is determined, procurement contract language can be drafted to define the delivery term to improve this issue. Some informants also reported that the period of objection as required by the procurement law created an artificial waiting period leading to apparent shortages. This can be examined further. The issue of delivery points to real shortages that are the result of poor processes. But these poor processes lead to opportunity for persons in key positions to take advantage and amplify the problem. For example it is reported that nurses collude with pharmacies outside hospital by telling patients there are no drugs and they must go to the outside pharmacy. When the system creates shortages this leads to opportunity for unprofessional behavior.

Distribution: FuFarma is the provider of distribution services including warehousing and delivery services to hospitals of drugs procured by the government. Until three years ago, it was a fully public agency and the sole provider of distribution services. Now it is quasi private, 65% privately owned and the remainder still public. For the first two years after it was privatized, it was the sole source provider of distribution but is reported to have won a competitive bid last year on the tender for distribution services.

FuFarma is obligated to deliver to hospitals according to a plan that is developed by the Hospitals/Planning Department. The calendar for procurement commences in July

when tender contracts are issued. Deliveries commence in the fall and by the period January to July the following year, shortages begin to appear in the hospitals. FuFarma arranges a contract between each hospital and each winning bidder. These contracts provide delivery terms, and require the delivery inspection process. It is not clear why a separate contract is necessary between each hospital and winning bidder and no one could explain this. As a result, there are more than a 1000 contracts executed at this phase of the distribution process. [xi] It is unclear why the tender documents, which should include a contract between the MOH and the winning bidder, do not address delivery issues sufficiently to dispense with the need for this step. This correction is highly recommended as it is a point of vulnerability.

FuFarma arranges deliveries according to the delivery plan given to it by the MOH. This plan does not seem to "time" deliveries according to the needs of the hospitals rather than a division of the quantities procured among the hospitals. FuFarma currently makes a delivery schedule at the end of each week for the following week by considering the efficiency of their logistics – in other words with the goal of filling their trucks rather than supplying the needs of the hospitals as they arise. The saline solution problem described earlier is a result of the delivery mistiming.

STOCK – OUTS AND EMERGENCY ORDERS

Until the summer of 2007, there was a system in place by which FuFarma could supply hospitals on an emergency basis from January to June from a list at specified prices established by the MOH. Hospitals would pay FuFarma from separate budgets. There is no accounting of this system to ensure that stock "sold" on an emergency basis is not the same stock procured by tender. When the current Minister took office he abolished this system thus at present there is no system in place for emergency supply. Hospitals have no budget for additional products. A minimum hospital formulary will reduce stock outs and emergency orders.

RECEIVING AND DISPENSING AT HOSPITAL

Receiving and dispensing at the hospital, hospital pharmacy, service and patient levels is another area in which there are significant weaknesses. There is no system in place to ensure that all the drugs ordered in procurement and delivered to FuFarma are then delivered to the hospital central pharmacy then to the floors/services and finally to the patients. It seems that there is no system in place at the point of hospital receiving to match what should be delivered from FuFarma. Nurses from the various hospital services pick up from the central pharmacy to stock the pharmacy at the service point. There seems to be some record made at this point, but thereafter no record is made at the service pharmacy point to the patient, other than doctors' orders in the patient file. There is no system to match these points.

TUHA is in the midst of developing an IT system to manage the inventory system from receiving to the patient level. This solution may serve as a useful pilot

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[xi] There are 42 hospitals and 26 vendors at least.

which can be scaled up to all hospitals and connected to the FuFarma inventory system. The building of this type of pedigree or inventory management system will greatly reduce waste, inefficient ordering and improve access to drugs for patients. It can also be the basis for quantification of the procurement commodity list.

PROCUREMENT SCORE 6.6--MARGINALLY VULNERABLE

The score on procurement indicates vulnerability to corruption, and is based mainly on the work of the Procurement Department and TC. The main weaknesses arise in the pre and post procurement segments of quantification, delivery and distribution. According to informants, overall the new procurement law has improved results and the importance of this national reform should not be underestimated. Continued improvements in the procurement process should be encouraged. Weaknesses include the lack of guidance to procurement office staff on the selection and decision making in regard to the type of procurement to conduct; domestic versus international, open or other. Also there seems to be no opportunity to group drugs by class of drug rather than value of total amount procured. This would provide opportunity to achieve efficiencies not presently available. These points are a function of the national procurement law, which though recently updated was not designed for pharmaceuticals in particular but could be amended in the law itself or by regulation to reflect the needs of the pharmaceutical system. Other weaknesses in the procurement system are the lack of an objective quantification method to determine the quantity of drugs to procure, SOP for the routine inspection of consignments and management information system. These points significantly reduced the score. The planning phase was reported to be the weakest in the system by informants and on this point this author concurs.

RECOMMENDATIONS

1. Pre-procurement:
    a. Develop and install a quantification system at all hospitals with a requirement to match needs lists with national essential medicines list and medical treatment protocols.
    b. Develop and install a method to count and verify drugs dispensed at hospital, the data of which is integrated with the quantification system.
    c. Develop method for quantification of procurement commodity list.
    d. Schedule tenders to correspond with consumption rate and draft contract language accordingly.

2. Post-procurement
    a. Develop and procure minimum formularies for all hospitals and maintain these as part of the regular procurement system.
    b. Require FuFarma to deliver accordingly and to respond to requests from hospitals for urgent needs.
    c. Develop emergency supply system.

   d. Track drugs from producer to patient. Install a pedigree requirement or other system to track who has possession of drugs from producer to patient.

  3. Price Controls
    a. Develop system to confirm original producer pricing.
    b. Integrate pricing mechanisms throughout pharmaceutical system, including declared prices, procurement pricing, and HII pricing.

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[1] World Bank HNP Statistics and World Health Organization Core Health Indicators for years 2004 as most recent year available from an external source.

[2] World Bank HNP Statistics and World Health Organization Core Health Indicators for years 2004 as most recent year available from an external source.

[3] T. Vian, K. Gryboski, Z. Sinoimeri and R. H. Clifford, *Informal Payments in the Public Health Sector in Albania: A Qualitative Study* (Bethesda, US: Partners for Health Reformplus Project, Abt Associates, Inc., 2004).

[4] Lewis M. Informal Payments and the Financing of Health Care in Developing and Transition Countries. Health Affairs, 26, no. 4 (2007):984-997.