

Improving Transparency in the Pharmaceutical Sector

Michele Forzley, JD, MPH
Forzley & Associates
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Agenda

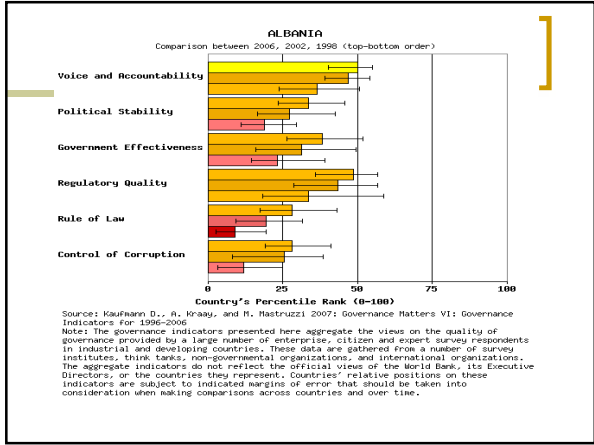
- Background on the study
- Governance and Defining Corruption
- Overview of Albanian health system
- Study findings - main problems
- Breakout session: prioritize solutions
- Recommendations, Closing, Next Steps
- Plenary session - Training on use of the tool

Background of the Study

- Why the study?
 - Goal: good governance and drug access
- Corruption and health systems.
- How the study was conducted.
 - WHO Methodology – the Tool
 - Quantitative and qualitative scoring
 - Identify weaknesses not actors

Quantitative Scoring

- 0.0 – 2.0 Extremely vulnerable
- 2.1 – 4.0 Very vulnerable
- 4.1 – 6.0 Moderately vulnerable
- 6.1 – 8.0 Marginally vulnerable
- 8.1 – 10.0 Minimally vulnerable



Corruption Defined

- Behaviors such as bribery, fraud, favoritism, collusion, embezzlement and other crimes and illegal acts.
- Conditions or failures in the procedures of the pharmaceutical system
 - No procedure exist.
 - Existing procedures are too weak to provide guidance. When coupled with low or no moral standards the system can be vulnerable to corruption.

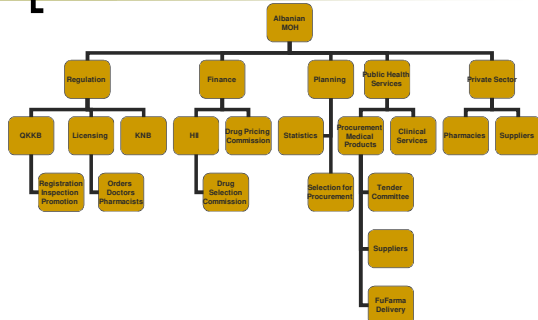
Good governance and cost drivers

- Metrics - a standard for measuring or quantifying something
- Process –guidelines or procedures
- Quality – desired features
- Transparency -comprehensible, plain, easy to find, in English

Albanian Health System 2007

- Publicly funded and delivered
 - Services and medical products
- Main functions
 - Regulation
 - Planning
 - Finance
 - Provision of services
 - Statistics and health information

Albanian Health System



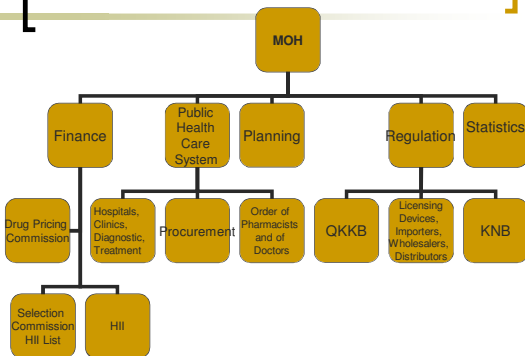
Pharmaceutical System

- Two parts
 - Public sector procurement
 - Private sector
 - Most drugs imported and some local production
 - Which drugs are reimbursed defined and paid by Health Insurance Institute
 - Private out of pocket payments

Key Five Functions of Pharmaceutical Systems

- 1. Procurement
- 2. Selection
- 3. Registration
- 4. Inspection
- 5. Promotion
- [\$ Finance is not a function]

Selection, Registration, Inspection, Promotion, Procurement



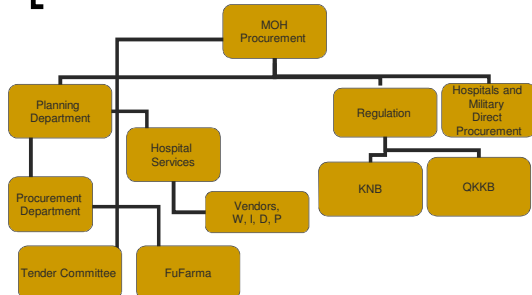
Albanian Pharmaceutical System

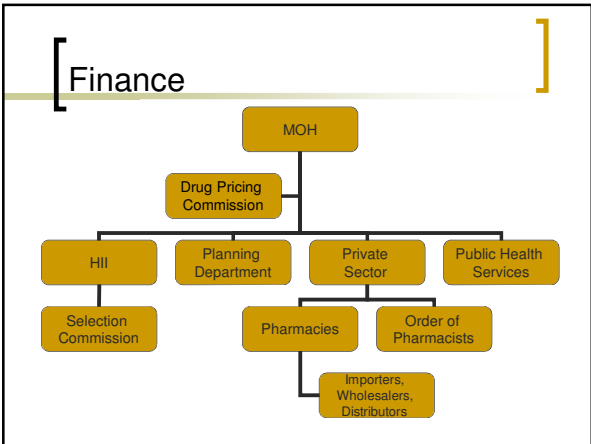
- Drug Registration
 - QKKB
 - KNB
 - Minister
- Drug Selection
 - HII Selection
 - MOH Planning and Procurement
 - Prescribing Practices
 - Minister
- Drug Promotion
 - QKKB
 - Order of Pharmacists

Albanian Pharmaceutical System

- Procurement
 - MOH
 - Hospitals
 - Private Sector Suppliers
 - Wholesalers
 - Importers
 - Pharmacies
 - Distributors
 - Manufacturers
- Inspection
 - QKKB
 - Imports
 - Manufacturers
 - Warehouse
 - Distributors
 - Procurement Team
 - Checks deliveries
 - HII – audit

Public Procurement





- Selection – Essential Medicines List (EML)**
- Identify drugs necessary to meet most health needs of population = EML
 - 1995 EML does not guide selection.
 - Four selection activities/bodies
 - Drug Commission on Reimbursement List
 - Komisioni I Nomenklatures se Barnave
 - Drug Pricing Commission
 - National Procurement – hospital list

- Selection**
- Score 3.6 Very Vulnerable to corruption
 - No methodology, or evidence based selection process.
 - Lack of guidelines for membership on DC
 - Professionalism
 - No standard operating procedures to guide decision making
 - No conflict of interest rules specific to drug system

Registration

- Marketing approval
 - QKKB, KNB and Minister
 - Only list of prescription drugs public
- Rules, laws and regulations
 - Not all in English
 - Not all available easily
 - Requirements and process incomplete

Registration Minimum Standards

- Up to date list of approved drugs – all that require registration - OTC and prescription. Details.
- Registration based on objective assessment of efficacy, safety, quality and accuracy of information in packaging.
- Requirements clear and objective, predictable process, guidelines on meetings with staff.

Registration

- Score 7.2 marginally vulnerable
 - Professional standards
 - Registration criteria – no reference to EML
 - Registration staff – QKKB
 - Criteria for selection to KNB
 - Prescription practices
 - No specific COI rules
 - No appeal system
 - No reports and no documents on line
 - Not all in English

Inspection

- Ensures operations are carried out in accordance with approved norms, standards and guidelines for drug production, quality control, storage, and distribution.
- Inspection of manufacturers and distributors.
- Requirements in law or regulation.

International Standards on Medicines Regulation

- Good Manufacturing Practice (GMP)
- Good Distribution Practice (GDP)
- Good Pharmacy Practice (GPP)
- Good Dispensing Practice (GDispP)

Inspection Minimums

- Power to inspect at reasonable time or place.
- Power to inspectors to enter place where drugs produced, stored, distributed or tested.
- Defines duties, responsibilities and powers in case of violations.
- Special ID document
- The rules are transparent.

Inspection

- HII Inspections – audit
- Procurement – post delivery inspection
- QKKB Inspections
 - Score 4.84 Moderately vulnerable
 - New staff – no regulations, no TOR
 - No GMP or GDP standards
 - No COI specific to inspections
 - Little experience no OJT

Promotion Minimum Standards

- Promotion is to influence intention to prescribe or purchase products.
- Regulations cover all activities –
 - Pre-approved advertisements to professionals and public
 - Qualification and training of medical reps.
 - Free samples, gifts, gimmicks
 - Post marketing scientific studies
 - Speaker fees and consultancies, conferences
 - Packaging, labeling and inserts
 - Exported drugs

Promotion

- Score 6.5 marginally vulnerable
- Current law
 - Only promote OTC drugs to doctors
 - No vitamin ads
 - Prescription drugs – only literature
 - If there are no rules how can they be respected?
- Order of Pharmacists
 - Code of governance and limited disciplinary power

Promotion Solution

- Develop regulations on promotion
 - Integrate international standards
- Increase professional standards for pharmacists and physicians
- Increase role and power of Order of Pharmacists to enforce and punish

Finance - Reimbursement

- Price Setting – Drug Price Commission
 - Base price
 - Margins for distributors, wholesalers, importers and pharmacists.
 - No selection criteria for membership
 - No COI on price setting
 - No standard operating decision procedures
 - Price declarations and negotiations by Minister
 - No international reference pricing
 - Estimated Score – 2.0 – very vulnerable

Procurement

- Transparent and explicit procedures
- Goals:
 - Price competition to ensure procurement prices are not higher than international reference prices.
 - Avoid cronyism and corruption
 - Best quality for the best price

Procurement

- Two quantification processes:
hospital needs ► commodity list
- No hospital minimum formulary
- Tender process
 - Size of tenders and advertising
 - Staff and Tender Committee reviews
 - Delivery terms and timing

Procurement

- Delivery
 - Deliveries are not staged to correspond to consumption rates
 - Until July 2007, little delivery confirmation
- Distribution
 - Contract between winning bidders and hospitals
 - Sole source distributor –FuFarma
 - Distribution plan – quantity only
 - Timing does not reflect hospital consumption rates
 - No minimum hospital formulary

Procurement

- Stock-Outs and Emergencies
 - No plan in effect – some hospital budget expenditure
- Receiving and dispensing at hospital
 - No tracking from central store to patient

Procurement

- Score 6.6 marginally vulnerable
 - Contract requirements
 - National procurement law too general for drugs
 - Lack of guidance to procurement staff on size of tenders, what is in each tender
 - No objective quantification system to develop commodity list, poor planning phase
 - No SOP for inspection of consignments
 - No management information system such as RFID

Break Out Sessions

- Five groups
- Select Rapporteur
- Tasks:
 - 1. Identify and prioritize solutions
 - 2. Does solution require external technical assistance? or internal working group? Or both?
 - 3. Who is on the internal working group?
 - 4. Do solutions need budget allocation?
 - 5. Pick deadlines for completion.
 - 6. Resume workshop at 12:30 pm

Next Steps

- Assessment √ ****
- Consultative process to develop and implement national frameworks to promote good governance in the sector
 - Commenced December 4, 2007 ****
 - Sufficient legal and regulatory framework
 - Procedures and methodologies
- Train all involved in the sector on the new framework.
- Measure Progress in 18-24 months

[Closing]

- Draft 2007-2013 Health System Strategy
 - Health system governance key priority
 - Access to drugs of good quality, efficacy and safety at affordable prices
 - Revision process for the health, drug and health finance laws

[Thank You]

For questions, comments or further information please contact:
Michele Forzley, JD, MPH
Director
Forzley & Associates
Global Health Lawyers and Consultants
mforzley@comcast.net
1-301-565-0680

[Plenary]

- WHO Tool Methodology
 - What is it and how do you apply it?
- Training on how to apply
- Adaptations for Albanian context
