Improving Transparency in the Pharmaceutical Sector

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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
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 – 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 Nomenklature 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**

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**Plenary**

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