Good Governance for Medicines

World Conference on Research Integrity
Lisbon, Portugal, 17 September 2007

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Unethical practices can be found throughout medicines chain & are very diverse

- R&D and clinical trials
  - Patent
  - Manufacturing
  - Registration
    - Falsification of safety/Efficacy data
    - Conflict of interest
    - State/regulatory capture
    - Thefts
  - Pressure
  - Unethical promotion
- Pricing
- Selection
  - Unethical donations
- Procurement & import
  - Overinvoicing
  - Cartels
- Distribution
  - Bribery
  - Collusion
- Promotion
  - Fraud
  - Evergreening
  - Counterfeit/substandards
- Inspection
- Unethical practices can be found throughout medicines chain & are very diverse
- R&D priorities
- Tax evasion
Corruption identified as the single greatest obstacle to economic and social development

- US$ 3 trillion spent on health services annually
- Global pharmaceutical market: > US$ 600b
- 10 to 25% procurement spending lost into corruption (including health sector)
- Some countries report that 2/3 medicines supplies lost through corruption and fraud in hospitals
- Low quality trials exaggerate the benefits of treatment by an average of 34%
- Bribery of high officials in regulatory authorities has led to unsafe medicines circulating on the market resulting in deaths
Unethical practices can have significant impact on the health system

- **Health impact**
  - Lack EM → increases morbidity & mortality
  - Unsafe medicines on the market
  - Irrational use of medicines

- **Economical impact**
  - Pharma. expenditure low-income countries:
    - 10-40% of public health budget
    - 20-50% of total health care expenditures
  - Poor most affected → inequalities

- **Image and trust impact**
  - Reduces government capacity
  - Reduces credibility of health profession
  - Erodes public trust
Corruption requires two parties: the corrupter and the corruptee

"Whose is the greater blame? She who sins for pay or he who pays for sin?"

Sor Juana Inés de la Cruz
WHO Good Governance for Medicines Programme

- **Goal**
  - To curb corruption in pharmaceutical sector systems through the application of transparent and accountable administrative procedures and the promotion of ethical practices among health professionals.

- **Specific objectives**
  - To increase the awareness of all stakeholders on the potential for corruption in the pharmaceutical sector and its impact on health systems functioning.
  - To increase transparency and accountability in medicines regulatory systems and supply management systems.
  - To build national capacity for good governance in medicines regulation and supply management systems.
Efforts to address corruption need coordinated application of two basic strategies

- "Discipline-based approach" (top-down)
  - Laws, policies and procedures against corruption and for pharmacy practice with adequate punitive consequence for violation
  - Attempts to prevent corrupt practices through fear of punishment

- "Values-based approach" (bottom-up)
  - Promotes institutional integrity through promotion moral values and ethical principles
  - Attempts to motivate ethical conduct of public servant
Good Governance for Medicines programme: a model process

**PHASE I**
National assessment

**PHASE II**
Development national GGM programme

**PHASE III**
Implementation national GGM programme

Assessment report

GGM officially adopted

Communication plan
Assessment of transparency and accountability

- Assesses vulnerability to corruption of systems in place
- Looks at key functions of the pharmaceutical sector systems
  - Regulation: registration, licensing, inspection, promotion
  - Supply: selection, procurement, distribution
- Elements evaluated:
  - Country's regulations and official documents
  - Written procedures and decision-making processes
  - Committees, criteria for membership and conflict of interest policy
  - Appeals mechanisms and other monitoring systems
Development of National GGM Programme

- Developed through a national consultation process with all stakeholders

- Components of GGM programme:
  - Ethical framework of moral values & ethical principles
    - Justice/fairness
    - Truth
    - Service to common good
    - Trusteeship
  - Code of conduct
  - Transparent and accountable regulations and administrative procedures
  - Collaboration mechanism with other GG & AC initiatives
  - Whistle-blowing mechanism
  - Sanctions on reprehensible acts
  - GGM implementing task force

National GGM programme

Discipline based approach
Values based approach

PHASE I
PHASE II
PHASE III
Implementation of National GGM Programme

- Strengthening systems by increasing transparency and accountability
- Promoting awareness (general public & health professionals)
  - Dissemination of information (newsletter, website, etc.)
  - Social marketing (radio, TV jingles, posters, etc.)
  - Critical thinking and discussions (seminars, conferences)
- Building capacity (managers and public policy makers)
  - Technical training programme
  - Leadership training programme
Bottom-up approach in implementation of project and policy development
"Corruption is a powerful force, but it is not inevitable or unavoidable. Diminishing its impact restores diverted resources to their intended purpose, bringing better health, nutrition and education to victims of corruption around the world, and with them, opportunity and hope."

Transparency International