Good governance in the pharmaceutical sector

Access to quality-assured, essential medicines and their appropriate use remains limited in many parts of the world despite recent progress in improving the availability, affordability, quality and safety of medicines. Many factors contribute to poor access including inadequate financing, high prices, fragile supply systems and structures, as well as the irrational use of medicines. Weak governance complicates access by fueling inefficiencies, distorting competition, allowing corrupt practices and hindering effective management.

Promoting good governance in the pharmaceutical sector makes a sustainable contribution to health systems strengthening and universal health coverage. Growing numbers of public health officials in ministries of health and national medicines regulatory authorities recognize the need for their institutions and personnel to work in more transparent and accountable environments.

To strengthen good governance, the impact of inefficiencies, waste and corruption needs to be recognized; transparency and accountability need to be improved; key stakeholders should be involved in development of policies; and ethical practices promoted. Good governance must be institutionalized.

Reducing unnecessary expenditure on medicines and using them more appropriately, and improving quality assurance, could save countries up to 5% of their health expenditure.

Examples of issues that may lead to weak governance

- Registration: Countries typically have a list of registered medicines, written procedures and a standard application form for submission of applications, and a committee responsible for registration of medicines. However, written documentation describing the composition and the terms of reference of the registration committee, and conflict of interest declarations for committee members, may not exist.
- Selection: Most countries have publicly available criteria and transparent procedures for the inclusion in (or deletion from) the national essential medicines list. However, the members of the selection committee may not be required to declare any existing conflicts of interest. Selection committee terms of reference are not always publicly available, and decision-making processes may not be transparent.
- Procurement: Countries generally use competitive and transparent procedures to procure pharmaceutical products as well as objective quantification methods for determining purchase quantities. However, audits of procurement offices, as well as the appeals process for applicants who have their bids rejected, are often either lacking or can be strengthened.

Key steps of medicines supply chain

- R&D and clinical trials
- Patents
- Manufacturing
- Registration and pricing
- Inspection
- Promotion
- Selection
- Procurement
- Prescription and dispensing

Impacts of weak governance

- Limited availability and shortages of quality-assured medicines
- Inappropriate selection and use of medicines
- Poor quality and inequitable health services
- Lost and wasted resources
- Loss of public confidence
- Withdrawal of donor contributions

Common elements of good governance as found in the literature

- Ethics
- Transparency
- Accountability
- Voice/Participation
- Consensus
- Responsiveness
- Effectiveness
- Efficiency
- Information/Intelligence
- Rule of law
- Regulation
- Strategic vision
- Equity
- Inclusiveness
- Policy formulation and planning

Good Governance in the Pharmaceutical Sector

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countries and territories were in various phases of GGM implementation across the six WHO regions. The GGM approach involves many national participants, including key stakeholders in the pharmaceutical sector and civil society.

The aim of a national transparency assessment is to provide a comprehensive picture of the level of transparency and potential vulnerability to corruption of the critical pharmaceutical sector functions.

On completion of the assessment, a report with the findings and recommendations for action is produced, providing a baseline for countries to revise and adjust their laws and policies, administrative structures and processes, and to monitor the country’s progress over time. This also provides a platform for discussion on developing a national good governance framework and for implementing a strategy for promoting good governance in medicines regulation, procurement and supply.

The WHO GGM approach is implemented through a three phase approach by ministries of health.

PHASE I: National transparency assessment

- Assesses level of transparency and vulnerability to corruption of the existing regulatory, procurement and supply systems
- Regulation: registration, licensing, inspection, promotion, clinical trials
- Supply: selection, procurement, distribution

PHASE II: Development of a national GGM framework

- Efforts to improve governance in the pharmaceutical sector need coordinated application of various strategies. The GGM experience shows that two basic strategies to promoting good governance are implemented: a ‘discipline-based’ approach based on the legislative and administrative reforms necessary to establish transparent systems; and a ‘values-based’ approach, which builds institutional and personal integrity through the promotion of ethical principles.

PHASE III: Implementation of national GGM programme

- Implementation of the national framework involves institutionalizing a good governance programme and ensuring that it is fully integrated within the ministry of health and other relevant national constituencies.

Key observations and lessons learnt from the GGM programme evaluation

- Control of medicines promotion is most frequently identified as vulnerable to corruption.
- Dedicated and motivated national team is required to address related issues effectively.
- Formal, written criteria to guide selection of members of key committees such as medicine selection committees are essential.
- Collaboration with all key stakeholders is critical to promoting ownership.
- Some countries reported benefit from engagement with other ministries, particularly finance and those responsible for tackling corruption, as part of cross-sector advocacy for good governance.
- Additional momentum is achieved when support emanates from high political levels, especially from the head of state.

Success factors in implementing national frameworks: country examples

As of 2013