

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.

Key steps of medicines supply chain



Reducing unnecessary expenditure on medicines and using them more appropriately, and improving quality assurance, could save countries up to 5% of their health expenditure¹

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 declaration forms 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.

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

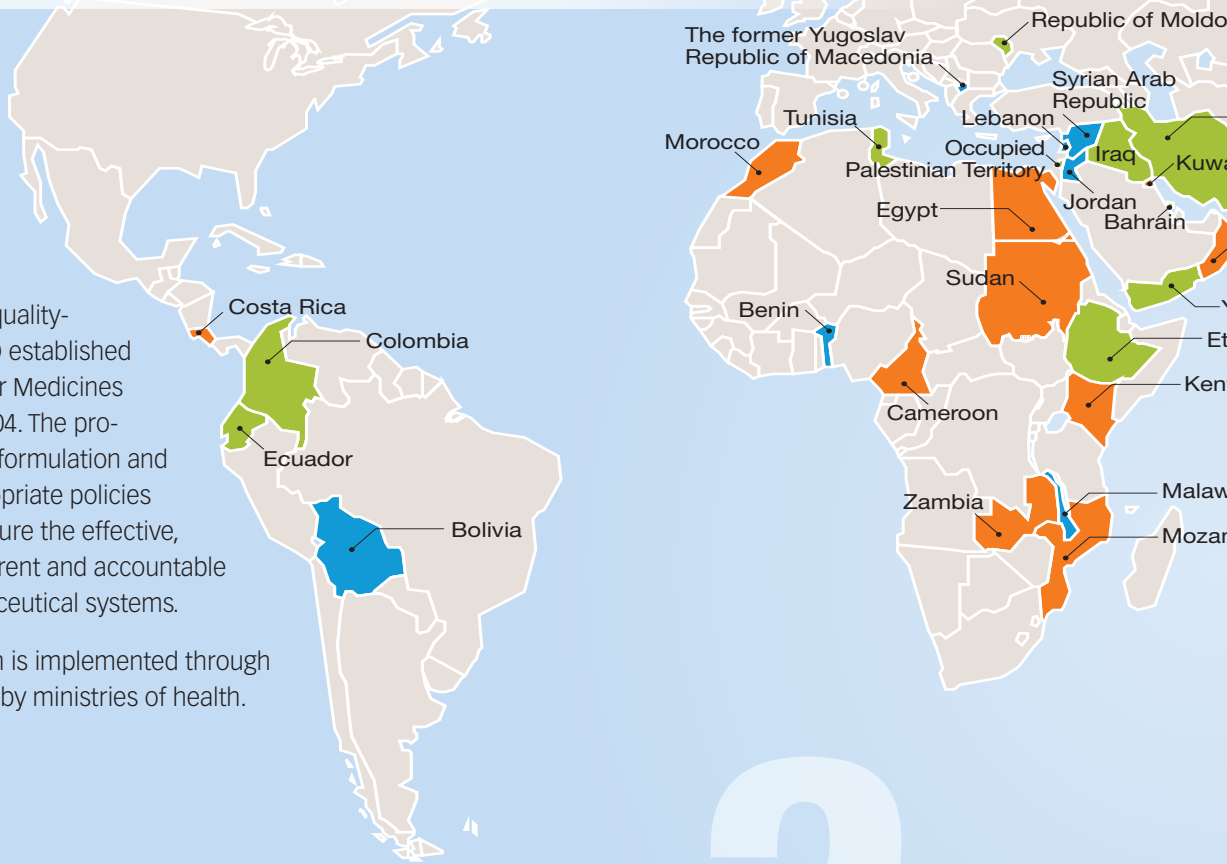
- Ethics
- Transparency
- Accountability
- Voice/ Participation
- Consensus
- Responsiveness
- Efficiency
- Effectiveness
- Information/ Intelligence
- Rule of law
- Regulation
- Strategic vision
- Equity
- Inclusiveness
- Policy formulation and planning

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.

IN ORDER TO ASSIST

member states to enhance governance in the pharmaceutical sector and promote access to quality-assured medicines, WHO established the Good Governance for Medicines (GGM) programme in 2004. The programme focuses on the formulation and implementation of appropriate policies and procedures that ensure the effective, efficient, ethical, transparent and accountable management of pharmaceutical systems.

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



1

PHASE I: National transparency assessment

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.
- Elements evaluated:
 - National regulations and official policy documents.
 - Written procedures and decision-making processes.
 - Committees, criteria for membership and conflict of interest policies.
 - Appeals mechanisms and other monitoring systems.

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.

2

PHASE II: Development of a national GGM

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.

This is translated in countries by various activities. For example, the revision of existing laws and procedures; development of a code of conduct for civil servants working in the pharmaceutical sector; the development of policies to manage conflicts of interest; and the development of operational guidelines to increase transparency in decision-making processes.



Success factors in implementing national frameworks: country examples

Political will/government support: Jordan

The Jordan Ministry of Health/Food and Drug Administration have demonstrated strong commitment and political will by involving not only the health sector but several other ministries, senior officials from public and private pharmaceutical organizations, representatives from consumer groups, local agencies concerned with good governance and others.

Alignment with existing legislation: Lebanon

Working teams studied the Model Framework in national workshops. Each team conducted a literature review to identify relevant general/specific Lebanese laws and policies of the Ministry, in relation to specific areas identified as deficient by the transparency assessment.

Integrating good governance: Thailand

Good governance was included in the academic curricula of the Faculties of Pharmacy and Medicine and incorporated in the Ministry of Public Health Plan since 2011. Since 2012, moral leadership and ethical principles have been promoted.

Collaboration among stakeholders: Mongolia

In January 2010, a good governance seminar was organized with the participation of key stakeholders from various sectors. The event enhanced awareness about good governance among private pharmaceutical organizations, improved their participation and collaboration towards good governance and identified several key barriers to compliance.

Acknowledgment of good governance: The Philippines

An awards programme encourages local government units, national health facilities and the private sector to develop and share innovative models of good governance.

Development of national framework

3

PHASE III: Implementation of national GGM programme

The approach proposed for Phase II is the development of national good governance for medicines frameworks. Once adapted to the national context, the national framework should be officially adopted to guarantee institutionalization within the legal, ethical and political structure in the ministry of health and in other relevant national constituencies.

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.

Among the common lessons that countries have learned through the GGM

programme are that national leadership (e.g. ministry of health, task force, steering committee) and policy support are essential, as well as multisectoral ownership and ongoing monitoring and evaluation.

Key observations and lessons learnt from the GGM programme evaluation²

- Countries have applied the GGM approach flexibly. Countries progressed through the various stages at differing rates and sequences, and with varying results.
- The most important factor influencing GGM performance in countries is the level of priority and support accorded to tackling corruption in general.
- 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.

Translating national frameworks into action

Worldwide, good governance in the pharmaceutical sector is being increasingly adopted in response to recognized widespread needs. The progress of each country depends on 'champions' who are dedicated to the success of the programme and have strong ethical leadership. Progress is also contingent on political will and support, as well as collaboration with key stakeholders and anti-corruption movements.

The first step towards improving governance in the pharmaceutical sector is to understand its structure, actors and motivations, and to identify the key points where inefficiency, waste and corruption can and do occur. Based on this, priority measures to improve governance at these points should be identified for the short, medium, and long term. Priorities should be based on the extent to which weak governance is a threat to safety and health in the first instance, and secondly, in relation to its economic implications. Regardless of what priorities are adopted, transparency and accountability mechanisms are critical at every point in the pharmaceutical sector in order to improve efficiencies, encourage competition, reduce cost and spending for medicines, and empower stakeholders, including the public.



Establishing ethical leadership and good governance through discipline-based strategies requires analysis and systematic work. This includes investment of public resources for the development and socialization of good governance approaches, and the provision of an adequate operational budget for their implementation.

Increasing access to medicines remains one of the major global obstacles to achieving universal health coverage. Governance has been identified as being crucial for universal access and sector performance, for example through increasing efficiency and reducing wastage. Good governance and the critical need for evidence on effective interventions to increase access have therefore been identified as priority areas of work by the *WHO Medicines Strategy 2008–2013*.³ WHO efforts to improve good governance in the pharmaceutical sector – through policy and regulatory support initiatives and programmes such as Good Governance for Medicines and the Medicines Transparency Alliance – have generated considerable insight into understanding how good governance can impact the availability and affordability of quality medicines. To date this diversity of examples from countries is unique in the landscape of health governance and provides a rich and valuable resource to establish a robust evidence base for developing policies that can increase access to medicines.

- 1 *World Health Report*. Geneva, World Health Organization, 2010.
- 2 *First evaluation of the Good Governance for Medicines programme (2004–2012)*. Geneva, World Health Organization, 2013.
- 3 *WHO Medicines Strategy 2008–2013*. Geneva, World Health Organization, 2008.



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Leading sources of medicines-related inefficiencies¹

Source of inefficiency	Common reasons for inefficiency
Medicines: underuse of generics and higher than necessary prices for medicines	Inadequate controls on supply-chain agents, prescribers and dispensers; lower perceived efficacy/safety of generic medicines; historical prescribing patterns and inefficient procurement/distribution systems; taxes and duties on medicines; excessive mark-ups.
Medicines: inappropriate and ineffective use	Inappropriate prescriber incentives and unethical promotion practices; consumer demand/expectations; limited knowledge about therapeutic effects; inadequate regulatory frameworks.
Health system leakages: waste, corruption and fraud	Unclear resource allocation guidance; lack of transparency; poor accountability and governance mechanisms; low salaries.

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