

Paper submitted for MENA HPF workshop on “Governance in Universal Health Coverage”

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Title: promoting good governance in the pharmaceutical sector

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1 Introduction

1.1 Good governance

Good governance is an essential factor for economic growth and sustainable development at all levels and within all sectors of society. The social and economic chaos, corruption and violence that proliferate in failed states clearly demonstrate the results that ensue when bad governance prevails. There are many different definitions of governance and good governance in the literature. Although the definitions do not always use the same terminology, there is an emerging general consensus that Governance is about managing the resources and affairs of society to promote the well-being of its members. The term Good Governance is increasingly used to emphasize the need for governance to operate with due regard for the rule of law and especially in a manner that is free of corruption. There is also growing consensus on the major characteristics of good governance. Good governance is participatory, consensus oriented, accountable, transparent, responsive, effective and efficient, equitable and inclusive and follows the rule of law.

Concretely, governance is about decision-making processes related to policy formulation and the way policies are implemented to assure effective and ethical management. If decisions are made with respect for the major characteristics of good governance and in line with an established ethical framework, then the implementation of policies in the various sectors such as health, education and agriculture, will lead to social wellbeing and economic progress.

1.2 Corruption in health systems: a focus on medicines

Globally more than US\$ 6.5 trillion is spent on health services each year. The value of the global pharmaceutical market is estimated at over US\$ 900 billion. Such large amounts of money are an attractive target for abuse, making the pharmaceutical sector highly vulnerable to corruption and unethical practices. For instance, Transparency International estimates that 10 to 25% of public procurement spending is lost to corruption, and in some countries up to two thirds of often scarce medicine supplies at hospitals are lost through corruption and fraud.

This is in part due to the high market value of pharmaceutical products as described above. Also, the pharmaceutical sector is highly regulated. Poorly defined and documented processes, lack of checks and balances, as well as lack of transparency will increase vulnerability to corruption. Equally, if institutional checks are too cumbersome and slow down processes, clients may be tempted to offer a bribe or a gift "to get things done". Another factor making the pharmaceutical sector particularly vulnerable to corruption is the information imbalance between the various players, such as manufacturers, regulators, health-care

providers and consumers. Information is not shared equally and not all players have the necessary information to make informed judgments and independent assessments of the quality, safety and efficacy of medicines.

Corrupt and unethical practices in the pharmaceutical sector can have a significant impact on the health system and the health status of the population:

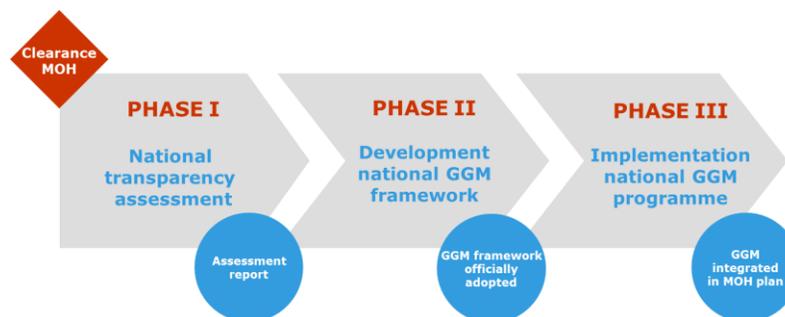
- a health impact as the waste of public resources reduces the government's capacity to provide good-quality essential medicines, and unsafe medical products proliferate on the market; it also leads to an increase in the irrational use of medicines
- an economic impact when large amounts of public funds are wasted. It is estimated that pharmaceutical expenditure in low-income countries amounts to 25-65% of total health-care expenditures, representing potentially major financial loss
- an image and trust impact as inefficiency and lack of transparency reduce public institutions' credibility, erode the trust of the public and donors, and lower investments in countries.

1.3 The WHO Good Governance for Medicines Programme

In an attempt to curb corruption in pharmaceutical systems, WHO established the Good

Governance for Medicines (GGM) programme. The programme's goal is to reduce corruption in pharmaceutical systems through the application of transparent, accountable administrative procedures and the promotion of ethical practices.

The GGM is implemented in a 3-step approach as shown below.



WHO has developed a technical package to help countries establish GGM programmes at national level. For Phase I, an assessment instrument "Measuring transparency in the pharmaceutical sector" provides a methodology to measure the level of transparency and the vulnerability to corruption in key functions of the pharmaceutical system. For Phase II a "Model Framework on Good Governance in the pharmaceutical sector" serves as a model for countries to develop their own national GGM framework, after wide consultation with key stakeholders and contextualization to national situations.

In the GGM programme, the focus is on the fundamental need to have good laws, regulations, policies and procedures in place to improve the management of the medicines chain and a corrupt-free environment to promote access to good-quality medicines. While corruption persists in pharmaceutical systems, it is almost impossible to ensure access to good-quality medicines for all members of society, and so improve people's health and wellbeing. The GGM programme's primary emphasis is on prevention

of corruption and on improving systems, rather than on identifying cases of corruption or individuals involved in unethical practices.

2 Situation in the EMRO Region

This summary of the situation on good governance for medicines in the Eastern Mediterranean Region builds in results from assessments on transparency and vulnerability to corruption in thirteen countries of the Region. The WHO instrument includes eight important functions of the pharmaceutical system namely: registration of medicines, licensing and inspection of pharmaceutical establishments, control of medicines promotion, control of clinical trials, selection of essential medicines, procurement and distribution.

The studies identified control of promotion/advertising of medical products as the highest priority in the Region, meaning that the function has the highest vulnerability to corrupt practices. This was followed by control of clinical trials and selection of essential medicines. The high vulnerability to corruption in these functions may have many reasons. The studies identified a few common factors which are deficient in the participating countries and which may be among the elements leading to the high vulnerability to corruption within these functions.

Legislations covering the pharmaceutical sector were found in most countries but some of these legislations lacked proper enforcement mechanisms and/or had low sanctions for reprehensible acts which affect the pharmaceutical sector. A number of laws were outdated and had not been revised for extended periods of time, reaching decades in some cases. Responsible bodies within the pharmaceutical sector to monitor the enforcement and application of legislations and regulations were lacking or met on ad hoc basis.

Technical committees responsible for decision making in the pharmaceutical sector lacked written criteria for selection of members and rotation policies. The committees did not have standard operating procedures for the decision making process and were not mandated to publish minutes of their meetings or details on the final decision, in the public domain. No policies for management of conflict of interest were found. In some cases, committee members and public servants were required to complete a declaration of interest form, but no appropriate systems for addressing the declared interests were reported. Procedures for applicants dealing with various public offices in the sector were not publically available and in most cases, no independent complaints/appeal mechanisms were in place and accessible to the applicants.

3 Lack of good governance: an inefficiency in health systems

One of ten leading sources of inefficiency in health systems, identified in the World Health Report 2010 was health system leakages: waste, corruption and fraud. The inefficiencies identified in the report are among the factors which may hinder countries' efforts towards reaching universal health coverage. Common reasons for this inefficiency were summarized as: unclear resource allocation guidance; lack of transparency; poor accountability and governance mechanisms; low salaries. Possible ways to address this inefficiency were to: Improve regulation/governance, including strong sanction mechanisms; assess

transparency/vulnerability to corruption; undertake public spending tracking surveys; promote codes of conduct.

Related to health products, the World Health Report 2010 also identified the following inefficiencies, all which could be linked to governance and prevalent practices in the sector. Underuse of generics and higher than necessary prices for medicines; use of substandard and counterfeit medicines; inappropriate and ineffective use; and overuse or supply of equipment, investigations and procedures.

The path to universal coverage, outlined in the report, involves three main tracks: raising sufficient funds, reducing reliance on direct payments to finance services, and improving efficiency and equity.

4 Key priorities for promoting good governance in the pharmaceutical sector in the EMR

The studies on transparency and vulnerability to corruption in the pharmaceutical sector revealed several important strengths in the Region. Among these were the following:

- Political commitment to increasing access to medicines
- Presence of medicines laws in all countries
- Active technical committees in various functions
- Registration systems
- Essential medicines lists
- Qualified human resources

The studies also identified some common gaps, accepted by the countries involved as areas in need of further efforts. Several initiatives have been initiated following the studies in various countries of the region.

- Policy for managing conflict of interest
 - Declaration
 - Management
 - Sanctions on violation
- Written guidelines on membership in committees (including rotation policies)
- Standard operating procedures (especially for decision making process)
- Public availability of information
- Control of medicines promotion
 - Direct to consumer
 - Medical professionals
- Civil society engagement
- Presence of suitable codes of conduct
 - Civil service
 - Professional association
 - Manufacturers association
 - Socialization of codes of conduct
- Rule of law

- Sanctions on reprehensible acts
- Enforcement mechanisms
- Guidelines on interaction between public officials and private sector
- Independent complaints mechanism
- Protection of whistle blowers
- Limited resources

5 Concluding remarks

Increasing transparency and accountability in pharmaceutical systems is an undertaking of considerable proportion and scale. In striving towards better systems, from a governance perspective, WHO and participating Member States acknowledge that it is still a relatively new and experimental field. The issues identified in the assessments, globally, have not been limited to developing countries. Governance of pharmaceuticals does not come in isolation from the overall governance system in countries. The WHO approach in this domain encourages sharing views and experiences across countries and utilizing the growing roster of human resources with technical expertise in the field. Involvement of stakeholders from outside the medicines sector is essential, due to the multi-stakeholder nature of good governance.

Among the main factors for success of initiatives in this sensitive area is the presence of national champions, who are dedicated & motivated for furthering this cause. The selection of appropriate national assessors and government counterparts was an important starting point for the formation of active national GGM teams. High-level political will & support as well as willingness and involvement of key stakeholders, such as anti-corruption agencies and civil society were extremely valuable. To reach any level of sustainability, the GGM functions should be integrated into existing structures and committees, at the national level.