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GOOD GOVERNANCE FOR MEDICINES PROGRAMME

Implementation in the WHO African Region and Beyond

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1. Introduction

The value of the global pharmaceutical market is in excess of US$ 600 billion. This makes the pharmaceutical sector very vulnerable to corruption and unethical practices. Even though data on financial losses are lacking, Transparency International estimates that, on average, 10 - 25% of public procurement spending, including in the health sector, is lost due to corruption[2]. Regardless of its level, corruption contributes to increased non-availability of medicines and undermines health outcomes as well as public confidence in health care delivery systems.

Corruption, in general, and in the health and pharmaceutical sector, in particular, is a complex problem and the World Bank has identified it as a major obstacle to economic and social development. In the pharmaceutical sector, corruption leads to non-availability of medicines. The risk of unsafe medicines being put on the market also increases due to counterfeiting and bribery of officials. The public loses confidence in their public health care delivery system and the ability of their Governments to provide appropriate health care. Since pharmaceutical expenditure in most countries represents almost half of overall health expenditure, corrupt pharmaceutical practices are also detrimental to national health budgets.

Why the "AFRO Pharmaceuticals Newsletter"?

The mission of the World Health Organization in the area of essential medicines is to help save lives and improve health. Medicines are an essential element in the provision of health care. However, even though they have a huge potential, the reality is that for millions of people, particularly the poor and disadvantaged, medicines are unavailable, unaffordable, unsafe or misused. Providing policy-makers and essential medicine managers with practical and evidence-based information is one important element of WHO's work. As a contribution towards achieving the above mission, the objectives of the "AFRO Pharmaceuticals Newsletter" are to:

- share information and experiences related to essential medicines and pharmaceutical policies with WHO Member States, partners in the pharmaceutical sector, health professionals and the general public;
- serve as a forum for the dissemination of information on the work of the WHO Regional Office for Africa in collaboration with Member States and headquarters, particularly in the following areas: medicines policy, access, quality assurance, rational use and traditional medicine.

The newsletter welcomes contributions from Member States, pharmaceutical sector partners, health professionals as well as the general public. They should be addressed to:

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2. WHO Good Governance for Medicines Programme

In order to contribute to curbing corruption in the pharmaceutical sector, WHO initiated the Good Governance for Medicines (GGM) Programme in 2004. The goal of the programme is to reduce corruption in pharmaceutical sector systems through the application of transparent and accountable administrative procedures as well as the promotion of ethical practices among health professionals. The underlying assumption to the above is that the more transparent a system is (documents and procedures easily available and known to all), the less vulnerable to corruption and other unethical practices it will be (and vice versa).

More specifically, the programme's aims are the following: increasing the awareness of all stakeholders on the potential for corruption in the pharmaceutical sector and its impact on the functioning of health systems; increasing transparency and accountability in medicines regulatory and supply management systems; and building national capacity for good governance in medicines regulation and supply management systems.

The nature of corruption and unethical practices is very diverse throughout the medicine chain, from the time a

1 With valuable contributions from *Guitelle Baghdadi-Sabeti* and *Fatima Serhan*, WHO Geneva.

2 GGM Programme Progress Report, February 2009. WHO/EMP/MAR/2009.1.

molecule is developed and the time it is marketed as a medicine. They include falsification of safety and efficacy data, theft, conflict of interest, unethical promotion, tax evasion, fraud, bribery, regulatory capture, unethical donations, and counterfeit or substandard medicines (cf. Figure 1). In some cases, inefficiencies in pharmaceutical systems can lead to the same results as corruption and can, therefore, be assimilated to corruption.

Fighting corruption in the pharmaceutical sector requires long-term efforts by all stakeholders. In its efforts to assist countries in curbing corruption, the programme recommends the simultaneous and consistent application of two basic strategies[3]:

- **Discipline-based Strategy**: This approach is based on establishing anti-corruption laws, legislation and regulations for the practice of pharmacy and foreseeing adequate sanctions for violations of the law. It is a **top-down approach,** which attempts to prevent corrupt practices through the fear of punishment.
- **Values-based Strategy**: This approach is based on building institutional (and individual) integrity through the promotion of moral values and ethical principles. This is a **bottom-up approach,** which attempts to motivate ethical conduct.

3. Implementation of the WHO GGM Programme

In order to implement the GGM Programme, WHO has adopted a three-phase approach[4]: assessment of the pharmaceutical sector, development of a national GGM programme, and implementation of the GGM Programme (cf. Figure 2). The first phase is preceded by a preliminary phase, during which clearance is sought from national authorities for implementation of the programme in a given country. This is a crucial step because without the commitment and political will of national authorities, implementation of the programme would be compromised.

Phase I: ***National Assessment of Transparency and Potential Vulnerability to Corruption*** of the systems in place, using a WHO standardized assessment instrument. It focuses on the following central regulatory and supply functions of the pharmaceutical sector: registration, licensing, inspection, promotion, clinical trials, selection, procurement and distribution.

The evaluation examines the existence and adequacy of regulations and official documents, written procedures and decision-making processes, technical committees and criteria for membership, conflict of interest policy, appeal mechanisms and other monitoring systems. The results and recommendations from the assessment are discussed and adopted by pharmaceutical sector stakeholders at a national workshop marking the end of Phase I.

The evaluation provides a picture of the level of transparency and potential vulnerability to corruption in the functions concerned. However, it does not measure the level of corruption, but rather the potential vulnerability to corruption.

Phase II: ***Development of a National GGM Programme.*** Based on the results and recommendations from the national assessment, a national GGM programme or framework is developed through a nation-wide consultation process. Once officially adopted, it will form the basis for improving the weaknesses observed in various pharmaceutical functions during the assessment.

Among other things, the programme should propose a framework of moral values and ethical principles, transparent and accountable regulations and administrative procedures, a mechanism for collaboration with other good governance and anti-corruption initiatives, a whistle-blowing mechanism and protection for whistle blowers, sanctions on reprehensible acts, creation and membership for necessary committees and in particular the GGM Steering Committee and the GGM Implementing Task Force. Increasing awareness on corruption issues, strengthening integrity systems and building capabilities for leadership should also be part of the framework.

Phase III: ***Implementation of the National GGM Programme.*** This will involve an integrated institutional learning process in the application of new administrative procedures for increased transparency and accountability in the following: strengthening systems by increasing transparency and accountability; building the capacity of managers and policy-makers on governance issues; promoting awareness of the general public and health professionals through printed materials, radio, television and electronic media.

As of May 2009, 26 countries in all the six WHO Regions had accepted and were at various stages of implementing the WHO GGM programme as shown in Table 1 below. The programme has largely been positively welcomed by many countries where fighting against corruption in all its forms is a topical issue. The increasingly open involvement of governments in the fight against corruption, alongside civil society organizations, anti-corruption agencies, academia as well as the private sector is raising public awareness of the problem, which in turn is demanding more concrete actions from governments on the issue.

Table 1: Implementation of the GGM Programme in WHO Regions

Region	Total Countries	PHASES		
		I	II	III
AFRO	7	Ethiopia, Kenya, Mozambique	Benin, Cameroon, Malawi, Zambia	--
AMRO	4	Ecuador, Colombia	Costa Rica	Bolivia
EMRO	5	Pakistan, Morocco,	Lebanon, Syria,	Jordan
EURO	2	--	Moldova, Former Yugoslav Republic of Macedonia	--
SEARO	2	Indonesia	-	Thailand
WPRO	6	--	Cambodia, Laos, Malaysia, Papua New Guinea	Mongolia Philippines
TOTAL	26	8	13	5

4. Implementation of the GGM Programme in the WHO African Region

In the WHO African Region, a total of seven countries are at various stages (see Table 1 above and details below) of implementing the GGM Programme: Benin, Cameroon, Ethiopia, Kenya, Malawi, Mozambique, and Zambia. Malawi was the first country to implement the GGM, based on a spontaneous request from the Minister of Health. An official request was submitted to WHO in 2006. Phase I training and the first national workshop were organized in 2007.

[3] WHO. GGM. Curbing corruption in regulation and supply of medicines. September 2007

[4] WHO. GGM. Assessment instrument. September 2007.

The other countries agreed to implement the programme after being solicited by WHO in June 2007. In all the countries, the local WHO offices, through the medicines advisors or other medicines focal points, are the first level facilitators for the programme, followed by the Regional Office and headquarters.

Rwanda agreed to implement the programme but the nominated assessors could not attend Phase I training to enable them to carry out a transparency assessment of the pharmaceutical sector. Through its Director of Pharmaceutical Services, during a meeting in Geneva in March 2008, the Republic of Congo also expressed interest in the GGM Programme. However, a formal invitation extended to the country to participate has since remained without response.

4.1 **Benin:** The national authorities accepted to implement the GGM programme in August 2007 and at the same time nominated two assessors and two government officials, who constituted the initial Benin GGM core group. The latter attended a training course in Geneva in September 2007 to enable it implement GGM Phase 1, i.e. assessment of the national pharmaceutical sector in Benin.

The results and recommendations of the assessment were discussed and the report adopted at a national workshop held in September 2008. The workshop also examined the elements of a national GGM programme and work plan to be developed. This workshop marked the end of GGM Phase I for Benin. The report is pending publication, and the next major activity is to develop a national GGM programme based on the recommendations of the assessment.

4.2 **Cameroon:** The country agreed to implement the GGM Programme in September 2007. The two assessors and government officials attended training on the use of the WHO Transparency Assessment Instrument in Lusaka, Zambia, in April 2008. This enabled them to embark on implementation of Phase I. They also attended Phase II training on GGM implementation at WHO headquarters, Geneva, in October 2008. A transparency assessment has now been completed and a draft assessment report was submitted to WHO in March 2009. A national workshop to discuss and adopt the report was held in Yaoundé in June 2009. On the same occasion a GGM Phases II training was organized.

4.3 **Ethiopia:** The country formally accepted to implement the GGM Programme in March 2007. Two assessors and government officials were nominated. One of the assessors, as well as the medicines national professional officer in the WHO Country Office attended training on the use of the WHO Transparency Assessment Instrument held in Lusaka, Zambia, in April 2008. A pharmaceutical sector transparency assessment has been undertaken and a draft report was submitted to WHO in April 2009.

4.4 **Kenya**: The national authorities agreed to implement the GGM Programme in March 2008 and nominated two government officials as well as two assessors. The latter underwent training on the use of the WHO Transparency Assessment Instrument in Lusaka, Zambia, in April 2008. An assessment of the national pharmaceutical sector was completed and a report is being finalized after a review, by WHO, of the draft submitted in August 2008. The results will be discussed with stakeholders during an upcoming national workshop.

4.5 **Malawi:** This was the first country in the African Region to start implementing the GGM Programme following a spontaneous request to WHO by the Minister of Health. Two government officials were nominated as well as two assessors from the local Management Sciences for Health (MSH) office. They were trained on the transparency assessment methodology in March 2007. An assessment report and recommendations were prepared and adopted by a national workshop in July 2007.

On 16 May 2008, the Ministry of Health of Malawi authorized WHO to publish the report. This was done in February 2009. The report was formally launched in July 2009. At the same time GGM training for Phases II and III was organized.

4.6 **Mozambique:** Following government acceptance in July 2007 to implement the Programme, two government officials and two assessors were nominated. The latter attended training on the use of the WHO Transparency Assessment Instrument in Geneva in September 2007. Thereafter, an assessment of the national pharmaceutical sector was undertaken. A draft assessment report is available pending the organization of a national workshop to adopt it as well as its recommendations. This will pave the way for the development of a national GGM programme and work plan.

4.7 **Zambia:** The country officially agreed to implement the GGM Programme in August 2007. The nominated government officials and assessors attended the Transparency Assessment Instrument Training held in Geneva in September 2007. An assessment of the pharmaceutical sector was undertaken. The results and recommendations from this exercise were discussed and adopted at a national meeting held in July 2008. A WHO GGM mission to Zambia in April 2009 assisted the GGM team with the finalization of the report, which is now pending publication. The mission also guided the team through the process of developing a national GGM framework.

The commitment to implement the GGM Programme expressed by national authorities in the above countries testifies to the importance they attach to curbing corruption in general, and in the pharmaceutical sector, in particular. In addition, government and non-government anti-corruption agencies, non-governmental organizations, consumer organizations and civil society groups expressed keen interest in participating in this exercise. This anti-corruption drive needs to be continuously supported by all pharmaceutical sector partners lest any registered gains be eroded away by the ever-increasing pressures on pharmaceutical sector actors to deviate from prescribed ethical practices.

5. Other anti-corruption initiatives

The GGM Programme was developed and launched by WHO in 2004. It aims at curbing corruption by promoting good governance in pharmaceutical systems. Its current focus is on increasing transparency in administrative structures and processes in eight pharmaceutical regulatory and supply functions, namely inspection, registration, licensing, promotion, clinical trials, selection, procurement and distribution.

In 2007, the Department for International Development (DFID) of the United Kingdom initiated a similar programme, the Medicines Transparency Alliance (MeTA), which is also implemented in collaboration with WHO. MeTA is a multi-stakeholder initiative (alliance of partners), involving national governments, civil society organizations, academics and other pharmaceutical sector partners. It aims at finding ways to improve information flows and increase transparency in the selection, regulation, procurement, sale, distribution and use of medicines in developing countries.

Two countries in the African Region (Ghana, Uganda) are currently implementing MeTA, and one (Zambia) is implementing both MeTA and GGM. In order to clarify the

roles of the two programmes and avoid duplication of efforts, particularly in countries where both programmes are being implemented, a draft MeTA / GGM Common Statement was prepared in August 2008. While the focus and approach of the two programmes are different, the statement emphasizes that they are both pursuing the same goal and they can work together at country level. MeTA and GGM are, therefore, complementary and mutually-supportive initiatives. If both are implemented in a country, they can join hands and share information, reports and people involved.

6. Conclusion

In most developing countries, governments can only afford a certain level of funding for health, in general, and for pharmaceuticals, in particular. This calls for the efficient use of such limited resources. The present political commitment from the current participating countries is encouraging and it has facilitated, not only the implementation of the programme, but also the creation of a core group of nationals well conversant with the programme and capable of assisting new countries through the process of implementing GGM.

Table 2: Major GGM Programme Events since 2004

Event	Date	Place
First training (bi-regional WPRO-SEARO) on WHO transparency assessment instrument	25-26 Nov.2006	Manila, Philippines
1st GGM Global Stakeholders strategy meeting	30-31 Oct. 2006	Geneva, Switzerland
Training on WHO transparency assessment	March 2007	Lilongwe, Malawi
GGM national meeting	July 2007	Lilongwe, Malawi
Informal global consultation on GGM Phases II and III.	19-20 Sept. 2007	Geneva, Switzerland
Inter-regional training on WHO transparency assessment instrument.	25-27 Sept. 2007	Geneva, Switzerland
GGM Global Stakeholders group meeting	03-05 Dec. 2007	Bangkok, Thailand
GGM inter-regional feedback workshop (training Phase II)	16-18 Dec. 2007	Amman, Jordan
Inter-regional training on WHO transparency assessment instrument	8-10 April 2008	Lusaka, Zambia
GGM national meeting	July 2008	Lusaka, Zambia
GGM national meeting	September 2008	Glodjigbe, Benin
Informal Global Consultation on GGM Phase III	01-02 Sept. 2008	Geneva, Switzerland
Global Consultation: Role of private sector in promoting good governance in the pharmaceutical sector	03 Sept. 2008	Geneva, Switzerland
GGM inter-regional feedback workshop (training Phase II)	8-10 Oct. 2009	Geneva, Switzerland
Phase III training for Jordan national GGM team	20-22 Jan. 2009	Amman, Jordan
First Global GGM human resources training	29 June / 03 July 2009	Geneva, Switzerland
GGM national meeting / Phase II training	10-12 June 2009	Yaoundé, Cameroon
Launch of GGM assessment report / Phase II-III training	13-15 July 2009	Blantyre, Malawi

Table 3: Key GGM Publications since 2004

Publication	Date	Place
Measuring transparency in the public pharmaceutical sector: assessment instrument (Phase I)	Latest version dated July 2009	Geneva, Switzerland
WHO framework for good governance in the pharmaceutical sector (Phase II)	Latest version October 2008	Geneva, Switzerland
Guidelines for promoting a framework for good governance in the pharmaceutical sector (Phase III)	Latest version January 2009	Geneva, Switzerland
Advocacy materials: GGM assessment instrument; GGM, curbing corruption in medicines regulation and supply; GGM progress report, February 2009	Website[5] updated frequently	Geneva, Switzerland
Measuring transparency to improve good governance in the pharmaceutical sector: 4 country assessment studies	2008	Geneva, Switzerland
Measuring transparency to improve good governance in the public pharmaceutical sector: a comparative analysis of 5 country assessment studies	January 2009	Geneva, Switzerland
Measuring transparency to improve good governance in the public pharmaceutical sector in Jordan	January 2009	EMRO, Cairo
Measuring transparency to improve good governance in the public pharmaceutical sector in Malawi	January 2009	Geneva, Switzerland
Measuring transparency to improve good governance in the public pharmaceutical sector in Lebanon	July 2009	EMRO, Cairo
Measuring transparency to improve good governance in the public pharmaceutical sector in the Syrian Arab Republic	July 2009	EMRO, Cairo

[5] http://who.int/medicines/areas/policy/goodgovernance/documents/en/index.html

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Figure 1: Diverse nature of unethical practices in the medicines chain

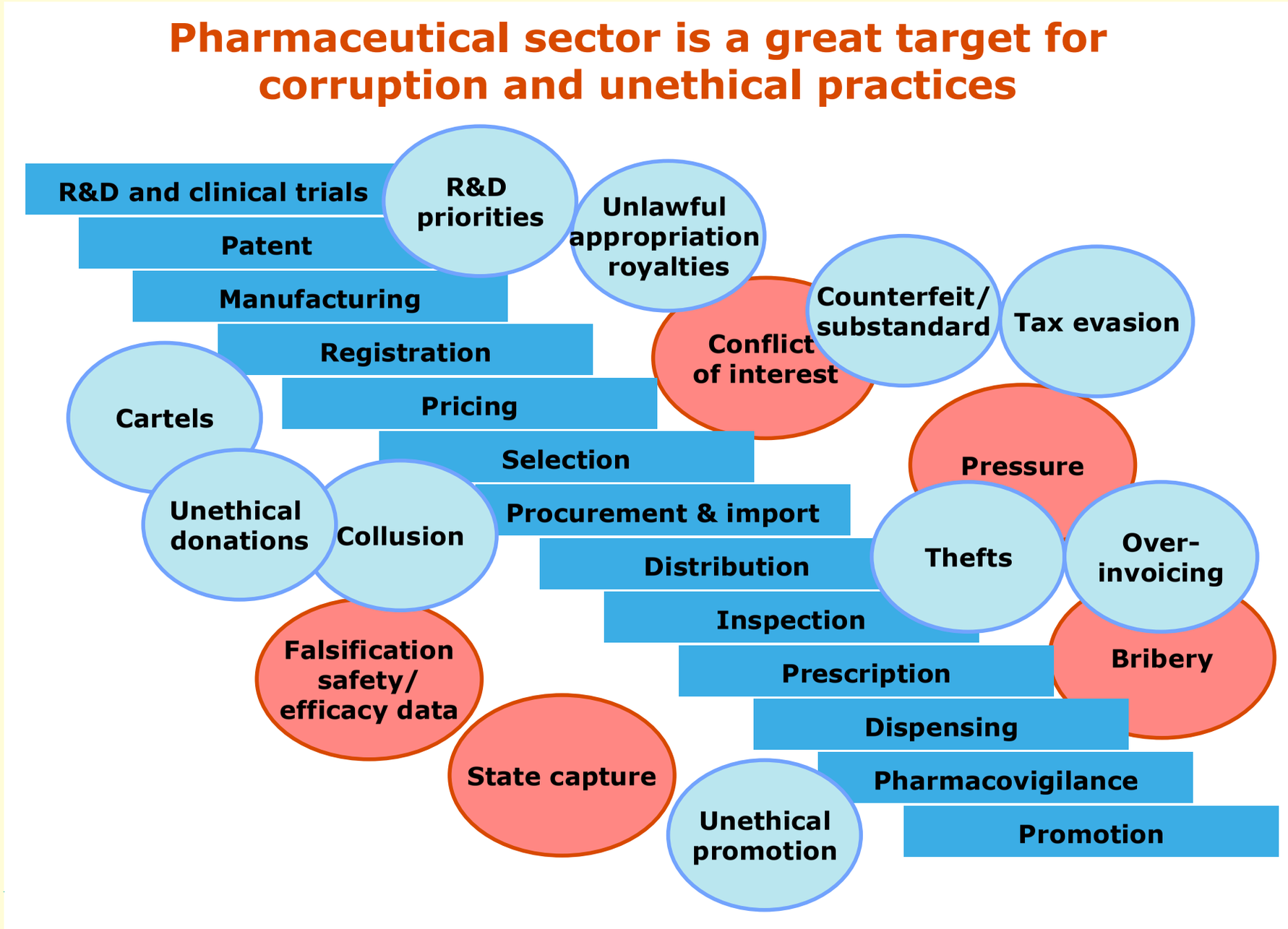

Figure 2: Phases of the Good Governance for Medicines Program