Measuring transparency in the Egyptian pharmaceutical system

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Dedication

To Yahia and Lama,

my contribution to the revolutionary Egypt
Abstract

The main purpose of this study is to assess the degree of transparency and accountability in the public pharmaceutical sector in Egypt. It aimed at providing an alarm about the weak points that could be vulnerable to corruption if measures to improve transparency and accountability are not introduced as soon as possible. The study uses a WHO transparency measuring instrument to assess one critical function of the pharmaceutical public sector as a case study; this function is medicines registration (product licensing). The study introduces a comparative analysis that sheds light on the position of the Egyptian pharmaceutical system compared to other 14 developing countries who conducted the same assessment.

In the recent few years, Egypt made important efforts to strengthen medicines regulatory and management systems especially those with regard to medicines registration; however; the assessment results showed that Egypt's transparency score is 5.04 on the 1 to 10 scale. This score is one of the lowest among the compared countries and it indicates that the pharmaceutical system in Egypt, specifically the medicines registration function, is moderately vulnerable to corruption, according to the WHO measuring instrument.

Some of the reported problems relate to opaqueness of the procedures of the registration process, especially those related to the registration committees. The selection criteria of the members, committees' composition and responsibilities and the mechanisms of decision making are the most opaque, in addition to the lack of any measures for accountability and conflict of interest. Moreover, some other problems are reported with regard to inefficiency and incompetence such as the lack of detailed procedures and guidelines for assessors and committee members, inexperienced assessors, inefficient incentive systems, violated timeframes,
miscommunication, contradictory and highly changeable regulations without taking enough time for studying before issuance.

Improving transparency in the sector and combating corruption need, first, strong anti-corruption legislations. Second, clear and transparent regulations and procedures should be introduced to decrease discretionary power. Third, this legislation and regulation should be effectively enforced via strong and efficient management and supervision systems.
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Measuring transparency in the Egyptian pharmaceutical system

Introduction:

Medicines are very important component of any health system worldwide. Medicines save lives and access to essential medicines is one entitlement of the right to health (Office of the United Nations High Commission for Human Rights [OHCHR], n.d.). That is why ensuring accessibility of affordable, effective and safe drugs is a critical public policy goal considered by every country. Governments pay increasing concerns to improve governance in the national drug authorities in order to be able to effectively formulate and implement pharmaceutical policy and regulations, and consequently accomplish health policy goals.

The pharmaceutical sector is highly regulated in order to overcome market imperfections and accomplish health policy goals. That is why literature suggests that it is susceptible to corruption as it could be subjected to pressure from certain commercial groups to maximize their interests, as a result, optimal decisions regarding medicines could be compromised. Policy makers should deal with these contradicting policy objectives in away that maximize public interest; however, this balance is not easily achievable. Different scholars have identified key functions of the government that should work optimally in order to achieve pharmaceutical policy goals. Improving governance of the pharmaceutical system requires ensuring transparency and accountability of these government's key functions.

Cohen, Mrazek & Hawkins (2007) identify key decision points in the pharmaceutical system and related processes that are vulnerable to corruption if the system is not sufficiently transparent and accountable. The World Health

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1 Pharmaceutical system refers to the relationship/interactions between the various actors of the pharmaceutical sector and the way decisions are made in particular in the government.
Organization [WHO] (2009a) identifies the main functions of the government related to these decision points that should be held transparent and accountable; these functions are registration, licensing, inspection of establishments, controlling medicine promotion, clinical trials, selection of essential medicines, procurement of medicines and distribution of medicines. WHO, USAID, WB conducted projects to assess and improve transparency and accountability in pharmaceutical sector in different countries; they covered most of the previously mentioned functions; the World Health Organization executed a three phase project for good governance and started in four pilot countries in 2004, now the project is progressing in 26 countries in different phases, the first phase is the assessment of transparency and accountability level in the pharmaceutical sector to detect vulnerabilities to corruption and put the suitable framework for improvement (WHO, 2010).

This research provides an assessment of transparency in the Egyptian pharmaceutical sector taking the registration (product licensing or market authorization) function as a case study. The WHO methodology is used in order to compare the result with the 14 published countries’ studies. This thesis sheds lights on the governance situation in the Egyptian pharmaceutical sector in relation to other developing countries and in relation to the overall governance indicators in the country. This in-deep analysis helps in prioritizing actions and putting policy recommendations to introduce improvement to the sector.

This thesis includes 5 chapters; first, the problem statement and research question. Second, the literature review. The third chapter is the methodology and the forth is the findings and results. Final chapter includes discussion of the results and recommendations.
Problem statement and research question

Governance is increasingly considered critical in development (Kaufman, Kraay & Mazruzzi, 2005), and accumulated evidence brings governance at the heart of the development. (Lewis, 2006) reported a correlation between poor governance on one hand and poor health status and ineffective health spending on the other, that is why developed countries direct large amounts of money to countries in which institutions show good governance.

One third of population worldwide lacks the proper access to effective, safe and affordable medicines, most of whom live in low and middle income countries (World Health Organization [WHO], 2004b). Poor access exists due to poverty, high medicine prices, poor health facilities and corruption. That is why pharmaceutical sector is a highly regulated sector by the government; this is to ensure well functioning pharmaceutical market and accomplish health policy goals. Literature identifies key functions of the government that should work optimally in order to achieve pharmaceutical policy goals. Ensuring transparency and accountability of these government's key functions is a must to improve governance of the pharmaceutical system (Cohen, Mrazek & Hawkins, 2007).

Although the Egyptian pharmaceutical sector represents the largest pharmaceutical base in MENA region supplying about 30% of the whole market (The Business Studies & Analysis Center [BSAC], 2006); the Egyptian pharmaceutical market is still very small compared to the global market. Many factors affect this situation such as low coverage of pharmaceuticals and high prices of medicines in relation to income that lead to a problem of affordability (World Health Organization/ Health Action International [WHO/HAI], 2004). On the other hand, the government gives a great concern to attract more investments to the sector and introduce regulatory
reforms in order to bring the sector to the international norms, and consequently improve market efficiency that will result in better access; however, some obstacles have been reported; United States Agency for International Development [USAID] (2009) reported that pharmaceutical regulatory process is opaque and vague, medicines registration and pricing lack transparency, clear accountability and timelines; as a result, long delays and discretionary decisions are reported. I could not find any previous work assessing governance situation in the Egypt's medicines regulatory system except some business reports that mentioned some problems related to inefficiency and opacity (Walby, 2010; Business Monitor International [BMI], 2009).

This thesis introduces an assessment of the Egyptian medicines regulatory authority in terms of good governance, it uses the WHO methodology to measure the degree of transparency and accountability of the sector and consequently its vulnerability to corruption based on Cohen, Mrazek & Hawkins’s (2007) metaphorical equation: monopoly + discretion- accountability- transparency = corruption. This thesis can help in deep diagnosis of the problem in order to reach to a suitable framework to design and implement the solution.

Due to time and effort limitations, I assess the degree of the transparency and accountability in the registration function in the regulatory authority, taking it as an example for its importance as the first step for any pharmaceutical product to enter the market, therefore, it should function optimally to ensure that medicines in the market are effective, safe and fairly priced. Further comparative analysis is done to compare the Egyptian situation with other 14 developing countries that conducted the same assessment; this deeper analysis sheds light on the patterns in other countries and helps to understand where we are standing.
This thesis is asking the research question:

"To what extent is the Egyptian pharmaceutical regulatory system transparent/vulnerable to corruption, and how does Egypt's performance in this sector compared to other developing countries"

Further specific questions are explored:

1- What is the degree of transparency and accountability of the registration process in Egypt’s Medicines Regulatory Authority?

2- What are the weak points in this process that are vulnerable to corrupted practices?

3- How is Egypt performing in terms of good governance in its pharmaceutical system compared to other developing countries?

4- How is the Egyptian Medicines Authority performing in terms of good governance compared to the overall governance situation in the country?

5- Based on the analysis, what are the next steps that should be taken for improvement?

**Conceptual framework:**

This thesis assesses transparency and accountability/vulnerability to corruption in the selected area in the public pharmaceutical system based upon Cohen, Mrazek & Hawkins’s (2007) metaphorical equation: monopoly + discretion-accountability- transparency = corruption. It tries to say that if we can improve transparency and accountability of the sector so we can decrease corruption and achieve good governance. The thesis provides knowledge about the depth, the extent
and the sources of poor transparency and accountability. This represents the first step for improvement and achieving good governance, and opening an informed dialogue between different stakeholders to promote governance and integrity of management practices in place. This thesis does not intend to provide evidence for the presence of corrupted practices; however, it just raises alarms for policy makers regarding the importance of implementing certain measures and actions to improve governance. By these measures; better access for medicines could be achieved.
Literature review:

I- Governance:

Governance is identified in the work of Kaufmann, Kraay and Zoido-Lobatón (1999) as "the traditions and institutions by which authority in a country is exercised". They identify six dimensions of governance according to the previous definition: voice and accountability, political stability and absence of violence, government effectiveness, regulatory quality, rule of law, control of corruption. The Worldwide Governance Indicators (WGI) project in the World Bank reports indicators for these dimensions in different 213 countries worldwide to assess aggregate and individual governance in these countries (World Bank, n.d.).

The United Nations Development Program [UNDP] (1997) identified governance as "the exercise of economic, political and administrative authority to manage a country's affairs at all levels". According to this definition, governance includes the mechanisms, procedures and institutions by which different groups meet their mandates and obligations, express their interests and practice their legal rights. Characteristics of good governance are identified by the UNDP (1997) as:

- Participation: all citizens should participate in decision-making, either directly or through institutions that convey their voices and represent their interests.
- Rule of law: laws should be fair and enforced and human rights should be secured.
- Transparency: free flow of accurate and enough information should be ensured for all who concerned with them.
- Responsiveness: all stakeholders should be properly served.
• Consensus orientation: bring all individuals to a consensus on what is the best for the group when formulating policies.

• Equity: all citizens should have equal opportunities to improve their well-being.

• Effectiveness and efficiency: processes and institutions should achieve results and meet expectations with the optimum use of resources.

• Accountability - Decision-makers should be accountable to the public, as well as to institutional stakeholders. This accountability prevents misuse and monopoly of power.

• Strategic vision for the future built on the understanding of the historical and presents responsibilities and mandates.

I.1. Governance and development:

Governance is increasingly considered critical in development (Kaufman, Kraay & Mastruzzi, 2005), and accumulated evidence brings governance to the heart of the development process. This is why developed countries direct large amounts of money to countries in which institutions show good governance (Lewis, 2006). Most of the international donors give great consideration to funding the investments in health sector in order to accomplish Millennium Development Goals. However, less consideration is given so far to effectiveness and accountability of health institutions, these governance issues are critical to accomplish health development goals. Lewis (2006) reported a correlation between poor governance - represented by corruption and ineffectiveness, on the one hand, and poor health status and ineffective health spending on the other. Armstrong (2005) reported that reaching the MDGs goals suffers from poor performance and one of the reasons is poor governance, mistrust in government performance falls within this poor governance,
and the solution is to introduce a service oriented public sector, based on transparent and accountable public institutions.

The United Nations described the concepts of integrity, transparency and accountability as founding principles of public administration that should be practiced by the UN and all member countries (Armstrong, 2005). Integrity is defined as “honesty” or “trustworthiness” in doing official duties, it represents the opposite to “corruption” or “the abuse of office” Transparency is defined as proper access by the public to timely and reliable information on decisions and performance in the public sector. Accountability is defined as "the obligation of public servants to report on public resources allocation and usage and offer justification for failing to meet standard performance". Armstrong (2005) argued that integrity, transparency and accountability are co-dependant.

In the same context, Klitgaard, Abaroa, & Parris (2000) argued that corruption flourishes in any system where there is monopoly of power over the service while there are no proper checks over the taken decisions; in addition they introduced the metaphorical formula: Corruption = Monopoly + Discretion – Accountability. Cohen, Mrazek & Hawkins (2007) added transparency to Klitgaard's formula to be: Corruption = Monopoly + Discretion – Accountability – Transparency. They argued that accountability depends on transparency and free flow of information about processes and procedures. In addition, stakeholders should have access to information about the decision making process in order to hold public officials accountable. Based upon this rationale, Cohen, Mrazek & Hawkins (2007) developed a framework to assess the pharmaceutical system in terms of governance; this framework was designed to help in identifying the
decision points that allow for monopoly and discretion and that could be highly vulnerable to corruption with limited transparency and accountability.

I.2. Governance in pharmaceutical system:

The importance of good governance in pharmaceutical system takes a raising concern recently; one reason is that one third of population worldwide lack the proper access to effective, safe and affordable medicines, most of them live in low and middle income countries (WHO, 2004b). Poor access exists due to poverty, high medicines' prices, poor health facilities and corruption. Vulnerability of the pharmaceutical system to corruption could limit the ability of the country to ensure good medicines access to population and consequently affecting health outcomes; therefore, improving governance in the pharmaceutical sector could be one of the determinants of good access (Cohen, Mrazek & Hawkins, 2007).

Why pharmaceutical sector is vulnerable to corruption:

- Medicines are profitable due to asymmetric information between patients on one hand and suppliers (industry, importers, wholesaler, prescribers and pharmacists) on the other hand (Cohen, Mrazek & Hawkins, 2007). Those suppliers could tend to maximize their profits far beyond what is allowed under existing regulations and professional ethics if proper regulations and procedures are not in place and/or enforced.

- The pharmaceutical sector is highly regulated by the government, therefore, some critical decisions could be monopolized by government officials if there are not transparent and clear procedures and criteria for decision making; and this in turn increases vulnerability to corruption "as corruption loves multiple and complex regulations with ample and un-checkable official discretion"
Klitgaard, Abaroa, & Parris (2000, p.26). Government intervenes to regulate the pharmaceutical sector because the pharmaceutical market is one of the least well functioning markets (Hollis, 2005); this is because the very specific characteristics of the pharmaceutical market such as monopoly practices by companies toward the relatively inelastic demand for some medicines (Docteur & Moïse, 2008) in addition to the asymmetric information resulted from uninformed patients besides unethical promotional activities that showed to influence doctors' prescribing behaviors. In addition, government has responsibilities in ensuring the efficacy and safety of all medicines (Norris, Herxheimer, Lexchin & Mansfield, 2004). This pervasive bureaucracy should have a framework for transparency and accountability otherwise public officials could deviate from norms (Cohen, Mrazek & Hawkins, 2007). For instant, the government is responsible for determining the price of medicines in the market through the pricing committee, if there are no clear and transparent procedure for selecting the committee, determining the price, prohibiting the conflict of interest and strong institutional checks and control; there could be discretionary decisions and wide variations between prices of the same medicines in different companies, e.g. Egypt case (USAID, 2009). This could result in high unjustified prices for some products while many companies escape the market due to inability to obtain fair prices, this consequently has a negative effect availability and affordability.

- The very complex supply chain of pharmaceuticals with almost thirty parties involved, thus, it is difficult to control and protect it from sub-standard and counterfeit medicines. (Cohen, Mrazek & Hawkins, 2007)
These causes of corruption in the pharmaceutical sector show that the pharmaceutical policy in the country should achieve a compromise between two conflicting policy stances. Poor functioning pharmaceutical market needs more regulatory control from government to correct market failure and protect patients; however, intensive regulations usually open the door for corrupted practices by public officials. Considering Egypt situation, poor functioning markets exist in most of the important industries not only medicines, recent crisis in food items and construction materials are good example of this market failure. This calls for strong regulatory system to control these market failures while introducing strong accountability and transparency measures to combat corrupted practices by public officials. Countries experiences also suggested the importance of proper regulations in the pharmaceutical sector; even developed countries with well-functioning economy introduce heavy regulations to the pharmaceutical sector.

In recent years, the corrupted practices in pharmaceutical system raise great concern and expert's discussions; Cohen, Kassirer, Bale & Williams (2006) reported some cases of corrupt and questionable practices in different key decisions points in the pharmaceutical system, these practices are usually found when there are unchecked interactions or unregulated conflicts of interests between pharmaceutical, biotechnology and medical device industries on one hand, and regulators and medical professionals on the other:

- One of the cases was in the registration process which represents the first decision point that the pharmaceutical product faces, this process aims at ensuring the safety and efficacy of the drug against a certain disease. Although this process needs to have transparent procedures that are applied uniformly with no discretion; Cohen et al. (2006) demonstrates a regulatory capture of the U.S.
Food and Drug Administration by the pharmaceutical industry lobby and decreased institutional integrity and independence. This regulatory capture was suggested after the high-profile inquiry into risks resulted from the use of the pain killer pills Vioxx, Bextra and Celebrex in 2004. This inquiry in addition to the fact that FDA recalled 12 major prescription drugs from 1997 to 2004, raise concerns about the ability of the FDA to make unbiased decisions.

- Other case was in medicines selection and treatment guidelines when the American Heart Association, the American College of Cardiology and the National Institutes of Health wanted to update their clinical guidelines, they hired nine experts to study the clinical trials data that had been published with the previous guidelines to put their recommendations, their recommendations included greater lowering of fats in diet, exercise and treatment with Statins (A group of drugs that treat hyperlipidemia and hypercholesterolemia). Although the selection committee consisted of a group of experts, it was revealed after they put their recommendations that seven of them are speakers or consultants for 5 companies that make statins, these financial arrangements between them and the industry raised questions about the bias in their recommendation.

- Other important case was reported in Nigeria in 2002 when public officials in Nigeria’s National Agency for Food and Drug Administration and Control (NAFDAC) involved in corrupted practices that exaggerated the problem of imported counterfeit drugs. Two NAFDAC officials released imported products without inspection and other two were caught taking bribe from a medicine dealer, in addition, the corrupted practices in registration process played a role in delaying products registration and open doors to unregistered products, staff
delay and drag the procedures to extort bribes from applicants to speed the process up.

The WHO identifies a three-fold impact of corruption on the pharmaceutical system: the *health impact* as the government's ability to secure good quality medicines will be minimized due to wasted resources, the *economic impact* as public funds for pharmaceuticals are lost, and the *mistrust impact* due to impaired transparency so government's credibility is lost and investments and donor's funds are decreased.

I.3. Improving transparency and decreasing corruption in pharmaceutical system:

Klitgaard (2000) identified three steps that countries make in fighting corruption, the first step is raising awareness of public official and decision makers about negative effects of corruption, the second step is identifying the degree of susceptibility of the government and take actions to decrease susceptibility to corruption and the last step is fighting corruption when it happens. Cohen, Cerccone & Macaya (2002) and Cohen, Mrazek & Hawkins (2007) introduce a framework to identify the potential hazards of corruption in the pharmaceutical system in order to guide the strategies to fight corruption and improve governance. This framework provide the description of key decision points and how they may be susceptible to corruption, suggesting measures to be taken in order to decrease these vulnerabilities. These key decision points are:

- Medicine registration, it is called also (product licensing and market authorization).
- Inspection.
- Facilities licensing.
- Medicines promotions control.
- Clinical trial control.
- Medicines selection.
- Medicines procurement.
- Medicines distribution.

The WHO initiated the implementation of its program (Good Governance for Medicines GGM), the program aimed at helping countries to develop a strategy to improve governance and fight corruption through three-phase process (WHO, 2010):
• First, assessing the degree of transparency/vulnerability to corruption in the pharmaceutical system to identify weak points and recommend the appropriate policies and procedures to address these weaknesses.

• Second, developing a framework for good governance in the pharmaceutical system based on the assessment results.

• Third, the implementation of good governance framework.

I.4. Transparency assessments in pharmaceutical registration in some developing countries:

According to the WHO standards, the registration process should include some essential steps: a clear legal basis, written clear guidelines and procedures, qualified and trained personnel, adequate secured premises and facilities, efficient committees made up of experts for informed decision making, independent appeal system, and finally all staff and committees should be held accountable to these procedures and guidelines. (WHO, 2009a)

After the inauguration of the WHO program "Good Governance for medicines", 26 countries have performed assessments for transparency/vulnerability to corruption in their public pharmaceutical system; however, only 14 countries that I could find their reports published in English language. These countries are Thailand, Malaysia, Philippine, Lao People's Democratic Republic, Syria, Costa Rica, Bolivia, Cambodia, Indonesia, Mongolia, Papua New Guinea, Malawi, Lebanon and Jordan. According to the study reports in these countries²

² The reports available at:
scores close to the average score of all the functions together unlike other functions that score very much lower below the overall average such as procurement in Costa Rica and promotion control in Jordan. This may suggest that the improvement will be easier in this function. Almost all of the countries have a published list of all registered pharmaceutical products except Malawi. Written procedures on how to apply for registration and standard application forms are there in all countries; however the dissemination of such information differs, Costa Rica has the highest score in this indicator while Malawi has the lowest. All the countries have committees that make different decision in the registration process; however, most of the countries lack terms of references for the selection of committee's members, policy for conflict of interest and publicly available detailed guidance on how the applications are evaluated by the committees.

, the degree of vulnerability to corruption in the registration process varied from 4.84 in Malawi to 9.4 in Costa Rica on the scale of 10. In the 14 countries, the registration process
II- Overview of the pharmaceutical sector in Egypt

II.1. Healthcare services:

Egypt spends 4.75% of the growth domestic product on health. Health spending declined from 6% in 2001/2002 to 4.75% in 2007/2008; this makes Egypt's health expenditures one of the lowest in the region. (Ministry of Health [MOH], Egypt & Health Systems 20/20 [HS 20/20], 2010) Healthcare is provided in Egypt through a fragmented and pluralistic system, the Ministry of Health is the main provider of health care in the country; it operates 4,300 health facilities with 66,440 beds all over Egypt and provides services with small fees, it includes primary care facilities (family health units and centers, maternal and child units), curative care facilities (central and general hospitals) (WHO, 2006b). 80% of the services including medicines are free; however, the MOH only spends 24% of the total health spending in the country while out-of-pocket expenditures reach 60%, 33% of which are on pharmaceuticals (MOH & HS20/20, 2010). Health Insurance Organization HIO provides health insurance coverage for 55% of the population, other governmental bodies provides services to small proportions of population such as teaching hospitals, university hospitals, Curative Care Organization CCO and ministries' hospitals (Defense, Interior, transport, …etc.).

II.2. Pharmaceutical sector:

The Egyptian pharmaceutical industry is the largest domestic pharmaceutical industry in MENA region constituting 30% of the market supply (BSAC, 2006). Companies in the Egyptian pharmaceutical market belong to one of three categories; Public sector companies that include 8 companies of the Drugs Holding Company, International companies and domestic private companies. Pharmaceutical spending
at retail value reached US$2.48 bn by the end of 2009 (BMI, 2010); however, it is one of the lowest per capita spending in the region. Although the government has committed to encourage foreign investments and target US$10bn by June 2010, only US$2.6 bn has been achieved by April. Most of the markets forecast are optimistic expecting more growth for the pharmaceutical industry in Egypt; this is because of the expansion of the domestic industry and increasing exports in addition to the attempts from the government to start a reform with regard to registration and pricing process and Intellectual property rights.

II.3. Pharmaceutical system:

The Egyptian Drug Authority is an organization under the umbrella of Ministry of Health; it is responsible for formulating and implementing policies and regulations to ensure access to effective and safe pharmaceutical products. The EDA contains three sub-organizations; two laboratories for research and control of pharmaceutical products and one regulatory organization. The Central Administration of Pharmaceutical Affairs (CAPA) is the regulatory body in the EDA that regulates and monitors pharmaceuticals to ensure efficacy, safety and affordability and availability of medicines. One of the goals of the organization is to enhance transparency and public trust. CAPA has four service-providing departments that perform the eight functions mentioned in the WHO instrument tool for measuring transparency; registration of medicines, licensing of pharmaceutical business, inspection of facilities, controlling medicine promotion, controlling clinical trials, selection of essential medicines, procurement of medicines for public sector and controlling distribution of medicines. (Egyptian Drug Authority [EDA], n.d.)
The registration process is responsible for "assessment of all Pharmaceutical products for human use including food supplements, veterinary products, insecticides, medical devices & cosmetics before giving registration license to ensure quality & safety of products with affordable prices by applying a Transparent-Effective -Smooth & Communicable System". (EDA, n.d.) However, some obstacles have been reported; USAID (2009) reported that pharmaceutical regulatory process is opaque and vague, medicines registration and pricing lack transparency, clear accountability and timelines; as a result, long delays and discretionary decisions are reported. I could not find any previous work assessing governance situation in the Egypt's medicines regulatory system except some business reports that mentioned some problems related to inefficiency and opacity (Walby, 2010; BMI, 2009b).

In this thesis, I assess the transparency/vulnerability to corruption of the registration process according to the standard of the WHO which states that the registration process should include some essential components: a clear legal basis, written clear guidelines and procedures, qualified and trained personnel, adequate secured premises and facilities, efficient committees made up of experts for informed decision making, independent appeal system, and finally all staff and committees should be held accountable to these procedures and guidelines. (A detailed list of registration essentials is provided in annex 4). This will be discussed further in the methodology section below.
III. Efforts to improve transparency and combat corruption on the national level:

Several efforts have been taken on the national level to safeguard against corruption; however, these efforts still have limitations so far:

- Egypt signed the United Nations Convention Against Corruption (UNCAC) in early 2005, after which some steps were taken.
- Cabinet Resolution No. 24 of 1 February 2007 put combating corruption a priority on the policy agenda.
- A Transparency and Integrity Committee (TIC) was established by the Minister of State for Administrative Development to conduct studies and develop recommendations to improve transparency, accountability and combat corruption. (TIC, 2008)
- Establishment of one-stop-shops in some public organizations (taxation and customs) to decrease red-tape and the person-to-person contacts and decrease the monopoly and discretionary powers of public officials. (TIC, 2010)
- The establishment of the Transparency Unit in the Ministry of Investment with UNDP supports to strengthen the legal basis for free flow of information and transparency. (TIC, 2010)
- Egypt joined the International Action for Good Governance and Combating Corruption; this includes OECD Good Governance for Development in Arab Countries Initiative, the Arab Anti-Corruption and Integrity Network (ACINET), the UNDP-POGAR project to support the Ministry of Investment in the fight against corruption and the MENA-OECD Task Force on Anti-Bribery. (Organization of Economic Cooperation and Development [OECD], 2009)
**Remaining Challenges:**

International and local assessment reports highlighted some remaining challenges and limitations that should be addressed and further efforts are needed:

- No comprehensive national strategy could be found and the Egyptian Penal code does not consider the growth of white-collar corruption and focus only on passive bribery, anti-corruption provisions are irregularly enforced, authorities’ efforts to raise awareness are still limited.

- The political will seems to be lacking during the past regime to make progress on fighting corruption; however, the coming days may show some improvement due to political changes.

- Recommendations from OECD (2009) and TIC (2010) reported the importance of the establishment of a national strategy based upon assessments of institutional conditions in different public organizations to identify inefficiencies that may lead to corruption. It is important to identify where are the areas of public administration that are most vulnerable to be corrupted. They recommend also strengthening of the legal framework to improve transparency, accountability and fight corruption.
Methodology

I. Basic aim of the research:

Based upon the situation of the Egyptian pharmaceutical public sector that has been discussed in the literature review, the importance of this sector for achieving health policy goals, and the importance to identify the areas of public administration that are susceptible to corruption and lack good governance. The aim of this research is to assess the degree of transparency and accountability in the Egyptian Drug Regulatory Authority in relation to the situation in other developing countries, taking the registration function as an example because it is almost the most complicated and the first step for the pharmaceutical product to enter the market. Knowing the degree of transparency and accountability sheds light on the degree of vulnerability to corruption (WHO, 2009a) as a warning signal; therefore, the next step in the research was to study what reforms and measures should be taken to reduce possible corruption and inefficiencies.

This research also provides a comparative analysis to assess the Egyptian situation in relation to other developing countries, to assess to what extent the registration process in Egypt follows the norms in the other countries, and to what extent the degree of transparency and accountability in the pharmaceutical sector is related to other aspects of good governance in the country. This analysis helps to identify where Egypt stands in applying good governance standard and what are the priority actions that should be taken.

II. Measuring transparency and accountability:

Different methodologies and analytic tools were used to assess transparency and accountability in the pharmaceutical sector; qualitative methods are widely used
in the form of semi-structured interviews with different stakeholders and focus
groups (USAID, 2005; Cohen et al. 2002; WHO, 2009a). In addition, different
measurement instrument have been developed to measure the degree of transparency
and accountability of the pharmaceutical system as a measure to vulnerability to
corruption. USAID (2005) developed an analytic tool to measure the integrity of the
selection and procurement of the pharmaceuticals by drug authorities, this tool is
based on USAID analytical framework; TAPEE – transparency, accountability,
prevention of discretion, enforcement of rules and standards, and education of public
officials. They formulated questions for each TAPEE factor, and then the results are
graded on a four point scale (poor, average, good or excellent) based on comparisons
to international standards and best practices. This grading indicates the vulnerability
to corruption; however, it does not verify whether the corruption will happen or not.

Cohen, Cercone & Macaya (2002) designed a diagnostic tool for measuring
transparency and accountability to be used by World Bank in assessing the
vulnerability to corruption in the countries' national pharmaceutical systems with
which they are working. This tool identifies key decision points with five functions
in the pharmaceutical system (registration, selection, procurement, distribution,
delivery and use), and measures the extent to which each of these key
decision points are transparent or vulnerable to corruption. The tool introduces sixty-
six indicators related to the five functions, each indicator is rated on a scale of five;
one represents the greatest degree of vulnerability, five represent the lowest and
three is the average. Then the final rating is calculated by aggregating the whole
indicators together. The survey is filled out by key informants from the different
stakeholders, and in addition interviews, surveys and focus groups are conducted to
measure the perception of corruption by patients, professionals and pharmaceutical industry.

In 2009, the World Health Organization published a transparency measuring instrument as a part of its Good Governance Project. It offers a complete methodology to do such assessment based on a questionnaire for date collection via interviews with relevant stakeholders in public and private pharmaceutical sector. The questionnaire is based on previous work of Cohen, Cercone and Macaya (2002); however, it is expanded to include 4 additional functions of the drug regulatory authorities: control of medicine promotion, licensing, control of clinical trials and inspection. The questionnaire introduces different indicators for each function, the rating takes place in a very similar way as with the Cohen, Cercone and Macaya (2002) indicators. The aggregated score of these indicators are used in addition to the qualitative part of the questionnaire including the views of interviewees, the notes and comments of the interviewers, the documents obtained during the study and other previous empirical studies. Thus, a comprehensive picture can be formed about the current degree of transparency/ vulnerability to corruption of these regulatory functions.

In my research, I assess only the registration regulatory functions as an example and so as to simplify the procedures of the research to be doable by a single researcher, I use the WHO measuring instrument covering the registration function as it is the simplest tool and the most applicable in the Egyptian context.
III. Questionnaire structure:

The questionnaire uses the WHO measuring instrument\(^3\) to assess transparency and accountability in the pharmaceutical sector taking the registration and pricing function as an example, the assessment is based upon quantitative measurement and qualitative information on structural indicators collected by interviewing stakeholders involved or related to the sector. The tool provides a list of questions answered by stakeholders by conducting semi-structured interviews with them. The questionnaire is provided in annex 2, annex 3 provides a full description of the questions’ rationale and method of interpretation as stated in the WHO measuring instrument. The interviews are semi-structured and flexible while collecting information from interviewees knowledgeable about the process, helping in exploring different ideas. (WHO, 2009a)

IV. Comparative analysis:

I compare the results I get from Egypt with the results of similar assessment that have been done in 14 developing countries. This is to assess the Egyptian situation in relation to other developing countries, to assess to what extent the registration process in Egypt follows the norms in the other countries. I compare the results about the level of transparency in the pharmaceutical system with the Transparency International (TI) Corruption Perception Index for Egypt in order to measure the extent to which the level of transparency and accountability in the pharmaceutical sector is related to other aspects of good governance in the country.

V. Selection of interviewees (Key Informants):

The interviewees should be related to or working in the pharmaceutical sector, selected to provide a mix of senior, middle and junior management who are knowledgeable and representing various types of institutions to obtain different perspectives. They are public officials, private sector persons and other related stakeholders (Academic professors, International organization's experts, professional organizations, etc.). The experience of the WHO showed that 10-15 interviews is enough to obtain good results and the goal is to interview enough people until the researcher feels that there is no extra information added. (WHO, 2009a)

Sixteen candidates have been contacted, but only 15 agreed to conduct the interview. The semi-structured interviews were conducted with them during April 2011. The results and analysis presented in this research represent the situation at this moment as some plans for improvement are being prepared now. The list of KIs includes 6 individuals from the public sector, 6 candidates from the industry, one candidate from a professional organization, one academic expert and one WHO consultant, see (Table 2).

VI. Rating indicators and interpretation guidelines:

Four methods are used to measure the degree of transparency. Methods 1 and 2 are used to score transparency/vulnerability to corruption for each function, and they are given equal weight in the final scoring. Method 3 assesses the existence of legal provisions, or administrative structures and procedures comparing them with their perceived application. Method 4 includes open-ended questions to allow for additional information and flow of ideas. (WHO, 2009a) Detailed illustration for the four methods paraphrased from the WHO measuring instrument is introduced in this section:
**Method 1:**

The availability of important documents to the public is assessed by asking the key informants whether they have certain knowledge about these documents or not. Questions in this category require (yes or no) answer to minimize subjective interpretations. Moreover, documents should be provided to support positive answers.

In this method, the answer of "yes" (existence of a document) equals a value of 1 and the answer of "no" (document does not exist) equals a value of 0. The score of 1 represents high degree of transparency and low vulnerability to corruption. On the other hand, the score of "0" represents low degree of transparency and high vulnerability to corruption. The lack of publicly available and detailed criteria or procedures increases the probability of discretionary practices and decisions.

"In summary:

– When the KI responds "yes" and the evidence is found, the score is 1
– When the KI responds "no" and the evidence is found, the score is 0
– When the KI responds "yes" and the evidence is not found, the score is 0
– When the KI responds "no" and the evidence is not found, the score is 0"

(WHO, 2009a)

**Method 2:**

Questions in this category involve a series of sub questions about the existence of a number of criteria. The existence of each criteria requires a binary answer (yes/no). As with method 1, each "yes" is given a 1, and each "no" a 0. If the KI does not know the answer, then the answer is "D.K." (Do not know). The total
score of the whole question is calculated by the division of the number of "yes" answers by the number of all valid answers, "D.K." answers are ignored and only (yes/no) answers are considered valid. The following example illustrates this method:

Indicator 3 "Are there written procedures for applicants on how to submit an application for registration of medicinal products?" includes seven criteria. If the answers are as follows:

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
<th>D.K</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written procedures</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Publicly accessible</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Describe the process to follow in submitting an application</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Mention timeframe for processing</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Mention fees</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Mention data to be submitted</td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Mention criteria for registration</td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The scoring of the indicator is then calculated as follows:

Total yes 4
Total valid answers 5
Scoring (total yes/total valid answers) 0.8

In this method, each indicator scores between 1 and 0. A value of 1 represents high degree of transparency and low vulnerability to corruption, a value of 0 represents low degree of transparency and high vulnerability to corruption. However, a figure between 0 and 1 also makes sense in this case. If a KI answers “D.K.” for the majority of the criteria, then the whole response for that particular indicator is counted as invalid and not be counted in the final scoring. Many "D.K." responses may give a distorted picture of the situation. (WHO, 2009a)
**Method 3:**

This method is used to measure Key Informants' perceptions toward some questions about the transparency level. This method represents "a cross-triangulation technique" to verify the collected data with method 1 and 2. Using the Likert Scale, the KI is asked to give his opinion on certain statement, he should respond whether he strongly agree - agree - is undecided - disagree or strongly disagree.

Example: indicator 11 asks the KI to what extent he/she agrees with the statement "The members of the registration committee are systematically selected based on the criteria in force in their country." The NAs then tick the answer given by the KI in the box on the questionnaire. After interviewing 15 KIs, a typical result might be as follows:

<table>
<thead>
<tr>
<th>Answers</th>
<th>Strongly</th>
<th>Disagree</th>
<th>Undecided</th>
<th>Agree</th>
<th>Strongly</th>
<th>N.A.</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>8</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Charts are used to present these results. More detailed information could be obtained from KIs about their perceptions and introduced in the narrative text. (WHO, 2009a)

**Method 4:**

These questions are open questions; this type helps to collect more ideas about the common unethical practices and the suggested improvement. Moreover, it helps to confirm data collected by method 1 and 2 and provides help in deeper analysis of the situation.
Scoring of each function:

After the completion of all interviews, the final score is calculated from only those indicators using methods 1 and 2, with the help of the score sheet in Annex 5.

1. For each indicator (using method 1 & 2), an average score was calculated by adding all the rates for each indicator and dividing the total by the number of valid answers ("D.K." answers "not applicable" are not counted). The average rating for each indicator is a value between 0 and 1.

2. All the indicators' average ratings are added together and divided by the number of the quantitative indicators (method 1 and 2) to obtain the final score of the registration function with a value from 0 to 1.

3. The result obtained is converted to a 0 to 10 scale by multiplying it by 10.

Example:

If the sum of the total average ratings of the 12 indicators is 8.60, then scoring for registration will be calculated as: 1. 8.60/12 = 0.716, then it will be converted to a 0 to 10 scale as: 0.716 x 10 = 7.16

The 10-point rating system is used to indicate the following degrees of vulnerability to corruption:

\[
\begin{align*}
0.0—2.0 & \quad 2.1—4.0 & \quad 4.1—6.0 & \quad 6.1—8.0 & \quad 8.1—10.0 \\
\text{Extremely vulnerable} & \quad \text{Very vulnerable} & \quad \text{Moderately vulnerable} & \quad \text{Marginally vulnerable} & \quad \text{Minimally vulnerable}
\end{align*}
\]

These final numbers help to determine the degree of transparency in the registration function. This is based upon the theoretical assumption of a reverse relationship between transparency and vulnerability to corruption.

There will be a narrative report integrates these quantitative information with additional qualitative information related to (methods 1 and 2) indicators that may
be mentioned by KIs during the discussions. The qualitative information collected with the (methods 3 and 4) indicators must be considered as well. The big aim here is to identify and learn more about the institutional weak point rather than obtaining more accurate quantification. (WHO, 2009a)

*Cross ‐ comparison of indicators*

The analysis should give special concern to the comparison between results of different indicators that assess the same information but with different methodology. For example, indicator I.8 “Are there clear written criteria for selecting the members of the committee?” (method 2) assesses the transparency of the procedures and rules set for the selection of the registration committee's members. At the same time, indicator I.11 “to what extent do you agree with the following statement: the members of the registration committee are systematically and objectively selected based on the written criteria in force in your country?” asks the KIs about their perception towards the application of these procedures in the real world. Sometimes the procedures and rules exist; however, they are not enforced, that is why indicator I.8 may score high while indicator I.11 scores low. The following table provides a list of comparable indicators, which can be used in the analysis. (WHO, 2009a)

*Table 1. Comparable indicators*

<table>
<thead>
<tr>
<th>Method 1 &amp; 2 indicators</th>
<th>Method 3 indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.8 and I.9</td>
<td>I.11</td>
</tr>
<tr>
<td>I.10</td>
<td>I.14</td>
</tr>
</tbody>
</table>

Source: WHO measuring instrument.
VII. Study Limitations:

- Despite being a measure for transparency and accountability with no attempt to identify whether corruption exists or not, this methodology still handles a sensitive issue and this may decrease the probability to reach a balanced list of interviewees. (WHO, 2009a)

- Sometimes the system has a proper level of transparency and still has corruption; this is addressed by the qualitative indicators that measure the perceptions of the interviewees and the observations of the researcher. (WHO, 2009a)

- If the interviewees are not selected carefully the results could be biased and depend on the interviewee's level of knowledge, their awareness of the system and their accuracy/openness in responding to the questions. The comparison of method 1 and 2 indicators to corresponding method 3 questions helps to minimize this bias. Information has been validated with existing evidence in the country (e.g. by finding and checking documents), and compared with the evidence provided in the replies of the interviewees. (WHO, 2009a)

- Due to time and effort limitations, in addition to the sensitivity of the issue and the difficulties to obtain a well balanced sample of knowledgeable interviewees about the process; I address only one function in the pharmaceutical system, which is registration (market authorization). It is very critical decision point as it is the first step for any pharmaceutical to enter the market. This narrowing is also important to be able to conduct deeper comparative analysis with other countries’ assessments. Although this limits the ability to generalize the findings to other functions in the pharmaceutical system, the comparative analysis shows us to what extent the degree of transparency is different between different
functions in other countries, permitting some tentative conclusions to be made on the likely situation in Egypt.

**Suggested improvement for the WHO measuring instrument:**

- Pricing is an important function of the pharmaceutical sector specifically in the countries which have no reimbursement system. In our region, most of the countries regulate prices through pricing committee that works according to a certain regulatory framework. Sometimes the pricing regulation is opaque or not enforced leaving a large gap for discretion. Assessing this function deeply gives important insight into the whole assessment.

- More perception indicators could be added that are relevant to quantitative indicators such as the existence of written procedures for applicant and the formal appeal system that is totally independent. This is because many key informants mentioned that these procedures and regulations are not enforced. The written procedures for applicant change from time to time and they are not applied uniformly, moreover, the independent appeal system is not applied and the appeals are reviewed by the same committee in most cases. Thus, measuring these perceptions would be useful to get accurate insight.
Results and findings

This section introduces the results of the questionnaire that was filled by 15 key informants through semi-structured interviews conducted with them during April 2011. The results and analysis presented in this research represent the situation at this moment as some plans for improvement are being prepared now. The list of KIs includes individuals from the public sector, industry, academic experts and professional organizations (Table 2).

Table 2: No. of KIs and their organizations

<table>
<thead>
<tr>
<th>Type of organization</th>
<th>Number of KIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government registration officers</td>
<td>6</td>
</tr>
<tr>
<td>Private pharmaceutical companies</td>
<td>5</td>
</tr>
<tr>
<td>Public pharmaceutical companies</td>
<td>1</td>
</tr>
<tr>
<td>Professionals organization (Pharmacists syndicate)</td>
<td>1</td>
</tr>
<tr>
<td>Academic expert</td>
<td>1</td>
</tr>
<tr>
<td>Consultant in pharmaceutical regulatory affairs in WHO/MOH</td>
<td>1</td>
</tr>
</tbody>
</table>

The results include quantitative score, indicators that represent perceptions of key informants, qualitative and quantitative data on each indicator and finally brief results in other countries' assessment.

1- Scores for each quantitative indicator and final score for the registration function:

The total score of transparency in the registration function is 5.04 on the scale from 1 to 10; scores for different quantitative indicators are listed below in (table 3).
Table 3: Scores for each quantitative indicator

<table>
<thead>
<tr>
<th>No.</th>
<th>Indicator</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Is there an up-to-date list of all registered pharmaceutical products available in the country?</td>
<td>0.57</td>
</tr>
<tr>
<td>2.</td>
<td>If such a list exists, does it provide a minimum level of information?</td>
<td>0.48</td>
</tr>
<tr>
<td>3.</td>
<td>Are there written procedures for applicants on how to submit an application for registration of medicinal products?</td>
<td>0.74</td>
</tr>
<tr>
<td>4.</td>
<td>Are there written procedures for assessors on how to assess applications submitted for registration of medicinal products?</td>
<td>0.38</td>
</tr>
<tr>
<td>5.</td>
<td>Is there a standard application form publicly available for submission of applications for registration of medicinal products?</td>
<td>0.76</td>
</tr>
<tr>
<td>6.</td>
<td>Are there written guidelines setting limits on how and where medicines registration officers meet with applicants?</td>
<td>0.69</td>
</tr>
<tr>
<td>7.</td>
<td>Is there a functioning formal committee responsible for assessing applications for registration of pharmaceutical products?</td>
<td>0.93</td>
</tr>
<tr>
<td>8.</td>
<td>Are there clear written criteria for selecting the members of the committee?</td>
<td>0.08</td>
</tr>
<tr>
<td>9.</td>
<td>Is there a written document that describes the composition and terms of reference of the committee?</td>
<td>0.25</td>
</tr>
<tr>
<td>10.</td>
<td>Are there written guidelines on conflict of interest (COI) with regard to registration activities?</td>
<td>0.09</td>
</tr>
<tr>
<td>12.</td>
<td>Are there clear and comprehensive guidelines for the committee's decision-making process?</td>
<td>0.15</td>
</tr>
<tr>
<td>13.</td>
<td>Is there a formal appeals system for applicants who have their medicine applications rejected?</td>
<td>0.93</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>0.504</td>
</tr>
<tr>
<td></td>
<td>Final score</td>
<td>5.05</td>
</tr>
</tbody>
</table>

Source: survey of KIs and author’s calculations

II- Indicators that represent perceptions of key informants:

The key informants were asked to give their perceptions on the following statements, (Table 4) summarizes their responses:

Table 4: Perceptions of KIs

<table>
<thead>
<tr>
<th>Indicator</th>
<th>% KIs answered with &quot;agree&quot;</th>
<th>&quot;strongly agree&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.11: The members of the registration committee are systematically and objectively selected based on the written criteria in force in Egypt.</td>
<td>20%</td>
<td>7%</td>
</tr>
<tr>
<td>No.14: Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on the final decision.</td>
<td>33%</td>
<td>13%</td>
</tr>
<tr>
<td>No.15: The registration committee meets on a regular basis and keeps minutes for its meetings.</td>
<td>60%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Source: survey of KIs and author’s calculations
III- Quantitative and qualitative data on each indicator:

I.1 Is there an up-to-date list of all registered pharmaceutical products available in the country?

Brief description of the indicator:

Official up to date list of pharmaceutical products should be available and easily accessible by general public. The list should include all information about all products approved for sale in the Egyptian market, any other product not on this list is considered non-approved and should not be used in the country. (WHO, 2009a)

Results on this indicator:

Eight respondents from the fifteen (more than 50%) reported that this list for all registered medicines in the Egyptian market can be found on the website, five respondents reported that it is not there, and one respondent said that it is not up-to-date.

The list is in fact available on the web site and dated February 24, 2011. The previous list was dated January 14, 2010, which indicates that the list is updated regularly. The lists of biological products and food supplement do not indicate the date; however, officers in the two departments reported that the lists are updated regularly. This indicator is interpreted using Method 1.

I.2 If such a list exists, does it provide a minimum level of information?

Brief description of the indicators:

The list should include sufficient information to ensure full government transparency. The availability of this detailed information about each product indicates how systematic the process of providing information from all companies is, and whether there are exceptions for some companies. Moreover, this available information provides a chance to health workers, pharmacists, dispensers and
patients to know about the products they use. This indicator is interpreted using *Method 2.* (WHO, 2009a)

_Results on this indicator:_

The list mentions most of the important information such as:

- Product name and composition.
- Dosage form.
- Packaging and price per pack.
- Name and country of manufacturer.
- Site of manufacture.
- Date of registration.

The lists lack only the validity of registration; however, it is well known by law that the validity is 10 years for all products. Only eight key informants mentioned that the list contains enough information.  

**1.3 Are there written procedures for applicants on how to submit an application for registration of medicinal products?**

_Brief description of the indicator:_

Detailed written procedures for applicant should be easily accessible on how to register a product. This helps to ensure the objectivity and consistency of the process in addition to avoiding confusion in communications between applicants and registration officers. The procedures should comprehensively describe every step in the process, data to be submitted, specify timeframe and fees, and clearly mention the criteria for registration with no exceptions to the standard requirements. This indicator interpreted by *Method 2.* (WHO, 2009a)

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4 Although the list is available, some key informants replied with no. The reasons were that the list is not well communicated, the website is a little confusing and some reported that although the list's date is recent, it does not contain all the registered products.
Results on this indicator:

The detailed procedures for submitting the registration inquiry are available on the website and the steps of the registration process are specified in the ministerial decree no. 296 of 2009. In addition, all data regarding the admission of stability and bioequivalence studies are available. These written documents are available on the website and determine the time frame for registration, while registration fees are specified in the ministerial decree no. 29 of 2009, which is publicly available as well. Although 12 key informants reported that there are procedures for the applicants to register their products according to the decree 296; 9 of them reported that these procedures kept changing with no clear notifications or written update for the amendments.

1.4 Are there written procedures for assessors on how to assess applications submitted for registration of medicinal products?

Brief description of the indicator:

There should be detailed written procedures for assessors on how to assess the applications, these guidelines should be publicly available, comprehensively describe process to follow in assessing submissions, specify timeframe for this assessment and the issues to be considered in assessing submissions, and provide guidance on report writing. This indicator is interpreted by Method 2. (WHO, 2009a)

Results on this indicator:

The assessors in the registration department have a check list according to which they assess the application files; it lists the documents that should be included in the application file. No written detailed procedures were found and only one key informant mentioned that such procedures exists, but are kept internally in the department.
I.5 *Is there a standard application form publicly available for submission of applications for registration of medicinal products?*

*Brief description of the indicator:*

This form is a tool to ensure the consistency of the registration procedures for all applications. This is important to foster fair market access. According to the WHO standards, this form should contain a description of the product, such as the name of the product (brand name and INN) and the composition per unit dose, brief summary of the manufacturing method, specifications of active ingredients and excipients, Summary Product Characteristics (SPC) and details of the packaging material and labeling. This indicator is interpreted by *Method 2.* (WHO, 2009a)

*Results on this indicator:*

There is a standard application form available on the website and all 15 key informants confirmed this. It lacks only minor information that is included in the WHO list such as the brief summary about the method of manufacture and specifications for ingredients and excipients.

I.6 *Are there written guidelines setting limits on how and where medicines registration officers meet with applicants?*

*Brief description of the indicator:*

There should be issued guidelines on how applicants can request appointments with government officials in order to monitor these meetings in a way that ensures full transparency and avoid conflict of interest or any other unofficial practice. This indicator is interpreted by *Method 1.* (WHO, 2009a)

*Results on this indicator:*

There are written procedures for applications submission. Applicants send an email to request an appointment and they receive a reply within 3 working days with
the appointments. For other inquiries, the registration departments usually publish the working hours and meeting place for company representatives on the bulletin board; this is not usually available on the website. Nine key informants confirmed the availability of these guidelines.

I.7 Is there a functioning formal committee responsible for assessing applications for registration of pharmaceutical products?

Brief description of the indicator:

There should be a formal committee consists of qualified and carefully selected members to evaluate and examine the admitted dossiers. This is to ensure that the process is participatory and transparent. This indicator is interpreted using Method 1. (WHO, 2009a)

Results on this indicator:

By law 127 of 1955, there should be a formal committee that is responsible for registration decisions called the Technical Committee for Drug Control. 14 key informants confirmed that this committee exists.

I.8 Are there clear written criteria for selecting the members of the committee?

Brief description of the indicator:

The members of the registration committee should be systematically and objectively selected based upon written publicly available criteria. According to WHO standards, these criteria include scientific and professional qualifications, exclude nepotism and conflict of interest and specify a timeframe for serving as a committee member. This indicator is interpreted via Method 2. (WHO, 2009a)

Results on this indicator:

No evidence was found that these criteria exist. The selection of the technical committee's members should be approved by the Minister of Health; there is no
limit for the members to stay in the committee. Eight key informants confirmed that such criteria do not exist while six key informants were unsure as to whether it exists.

**I.9 Is there a written document that describes the composition and terms of reference of the committee?**

*Brief description of the indicator:*

This document is very important to be published in order to ensure full transparency and to hold the members accountable. This indicator is interpreted using method 2. (WHO, 2009a)

*Results on this indicator:*

Seven key informants reported that there is a document that describes the composition of every committee; however, it is confidential and it contains only the names of the members without details about responsibilities, quorum requirements or timeframe for membership. Four key informants reported that this document does not exist and the other four key informants have no information about it. No evidence was found to confirm the existence of such a document.

**I.10 Are there written guidelines on conflict of interest (COI) with regard to registration activities?**

*Brief description of the indicator:*

The officials involved in medicines registration should be aware of the effects of conflict of interest on their decision making process. COI policy or guideline will oblige them to declare officially any potential conflict of interest that could affect their decision. These guidelines should be written and publicly available. The COI policy should include a standardized "declaration of conflict of interest" form, definition of what a COI is, rules on accepting gifts, rules on
reporting COI, mechanism for informers protection, actions to be taken in case of failure to comply with guidelines, mechanism for collecting evidences of enforcement of these regulations. This indicator is interpreted Method 2. (WHO, 2009a)

Results on this indicator:

No evidence is found with regard to these guidelines; all the key informants answered with either "No" or "do not know".

I.11 To what extent do you agree with the following statement: "The members of the registration committee are systematically and objectively selected based on the written criteria in force in your country"?

The responses of the key informants are summarized in (Table 5).

Table 5: Perceptions of KIs toward the selection of committee's members

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Undecided</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>N.A.</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private Co.</td>
<td>2</td>
<td>2</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>2</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: survey of KIs and author’s calculations

Figure 1: perceptions of KIs toward the selection of committee's members

![Figure 1](image_url)

Source: survey of KIs and author’s calculations

I.12 Are there clear and comprehensive guidelines for the committee's decision-making process?

Brief description of the indicator:
Decision making process should be fair and consistent that is why the committee should operate according to clear and comprehensive guidelines. These guidelines should be fully transparent and describe in details how the decision is made. The committee should then provide an official written report on each decision based on the systematic and participatory decision making process. According to WHO, these guidelines should include description of the committee mandates, specify the proper number of meetings, specify procedures, describe reporting structure and describe how these decisions will be disseminated. This indicator is interpreted using Method 2. (WHO, 2009a)

Results on this indicator:

No evidence was found about the existence of these guidelines; 9 key informants reported that no guidelines are there for making the registration decisions, while 3 reported that there are some sorts of guidelines; however, these guidelines are not available in written form for public. The remaining 3 key informants have no information about the existence of these guidelines. There was a common perception among almost half of the key informants that the decision making process is not democratic at all, and usually one member dominates in most of the decisions; moreover, some key informants reported high discretionary power in the committee's decisions.

I.13 Is there a formal appeals system for applicants who have their medicine applications rejected?

Brief description of the indicator:

There should be a formal system to receive concerns and complaints from applicant about their rejected products. There should be a chance for them to provide reasons and/or supplementary documents to support their evidences. This process
should be clearly regulated and organized by a formal appeal system to ensure full transparency. (WHO, 2009a)

**Results on this indicator:**

Ten of the key informants reported that there is an independent committee that reviews the appeals; however, other four key informants reported that the appeals are reviewed by the same committee as made the decision.

I.14 To what extent do you agree with the following statement: "Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on the final decisions"?

The responses of the key informants are summarized in (Table 6).

| Table 6: Perceptions of KIs toward the effect of benefits and gifts on the committee final decision |
|--------------------------------------------------|-------------------|----------------|----------------|-------------------|------------------|-----------------|-----------------|
|                                                   | Strongly Disagree | Disagree | Undecided | Agree | Strongly Agree | N.A. | D.K.  |
| Government                                       | 1                 | 1        | 1         | 2     | 1                |      |       |
| Private Co.                                      | 1                 | 2        | 1         |       | 1                |      |       |
| Others                                           | 2                 | 1        | 1         |       | 1                |      |       |

Source: survey of KIs and author’s calculations

I.15 To what extent do you agree with the following statement: "The registration committee meets on a regular basis and keeps minutes for its meetings"?

The responses of the key informants are summarized in (Table 7).
Table 7: Perceptions of KIs toward the regularity of committee meetings

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Undecided</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>N.A.</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government</td>
<td>3</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private Co.</td>
<td>1</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: survey of KIs and author’s calculations

Figure 3: Perceptions of KIs toward the regularity of committee meetings

I.16 In your opinion, what types of unethical behaviour are common in the registration system in your country?

- Five key informants mentioned discrimination.
- Eight key informants mentioned favoritism for the sake of some companies due to either good reputation of these companies or other different interests in these companies.
- Four key informants reported conflict of interest.
- Only one key informant mentioned bribes, noting however, that their frequency decreased to a large extent in the recent years.

I.17 If you were in a position of highest authority, what would be the first action that you would take to improve the registration process in your country?

The most frequent answers:
• Introducing consistent and comprehensive regulatory framework for the registration process so as to prevent controversial regulatory decrees and prohibit retroactive implementation of new decrees to include past cases.

• Identifying and enforcing a specific and consistent timeframe for the registration process.

• Registration pharmacists, who assess the applications, should take technical training on pharmaceutical industry and the registration procedures according to international standards.

  Moderately frequent:
  
• Identifying recruiting and promotion criteria for public official based upon experience, skills, performance and professional qualifications.

• Ensuring full transparency of all activities, procedures and guidelines.

• Identifying specific and clear responsibilities for the committee members, putting a clear mechanism for decision making and enforcing it and putting criteria for rotation of the committee members.

• Improving work conditions (suitable premises, salary and incentives system)

• Developing clear and comprehensive written guidelines on each step in the registration process and ensuring full transparency for each step.

• Conducting training for registration officers on communication skills and customer service.

• Introducing a new recruiting system based on hiring criteria.

• Registration procedures should be harmonized and uniformly applied on all cases.

• Establishment of totally independent appeals system.
• Recruiting highly qualified experts to senior positions not young unqualified officers.

• Registration officers on the front office should be well trained not freshly graduate with no experience in communicating with people.

  *The least frequent answers:*

• Developing a regulatory framework up to the international standards, using CTD\(^5\) model as a framework for the registration process and train the pharmacist in the registration department on how to review the applications using CTD model.

• The technical committee should contain experts in pharmaceutical industry not only academic persons.

• Establishing a system that receives complaints related to registration and act to solve it in a responsive and efficient way.

• Enforcing the timeframe on the companies in a way that cancel the registration if the dossier completion and the procedures do not happen in the scheduled timeframe.

• Studying the market before taking decisions about the number of generics allowed for every brand.

• Increasing the number of sub-committees to speed up the process and enforce timeframe.

• Restructuring the registration of food supplement products to be more organized and regulated.

\(^5\) The common technical document (CTD) is an agreement to assemble the quality, safety and efficacy data needed for registration in a common format in all countries in order to implement good review practice and ease the submission process for industry. (ICH website)
• Although the fees are mentioned in a ministerial decree; however, there are some extra fees during the process for example fees for completing missed documents; therefore, that is why there should be unified reasonable fees for the whole registration process.

• Pharmaceutical policies should be directed toward public interests, taking into consideration the social welfare while formulating economic policies that regulates pharmaceutical market.

• Pricing policies should give incentives only to the medicines that are needed in Egypt according to accurate disease maps for the Egyptian population.

Conclusion about the registration process drawn from the interviews and the related documents:

The registration of pharmaceutical products in Egypt takes place via the registration department in the Central Administration of Pharmaceutical Affairs in the Egyptian Drug Authority. Any medicine should be registered via this body and be assigned a Ministry of Health Registration number before it is marketed in Egypt. Registration rules and procedures are regulated through the ministerial decree no 296 of 2009. Key informants from the private sector reported weak adherence to the decree and large variations among registration of different products. According to the decree, the process should start by sending a registration submission inquiry form via email to the registration department. The department then makes an appointment within 3 working days for application submission. The company receives a reply after 15 working days from the submission date either rejecting their request or giving preliminary approval to proceed in the registration process (this notice is called the action letter).
Rejection at this stage is usually because there is no vacancy in the box of similar products. It is not allowed for registered generics to exceed a certain number in the market. Other reasons include an incomplete file or unclear or incorrect information. Procedures and forms needed for this submission inquiry are publicly available on the EDA website. After the primary approval, the company should apply for pricing within 30 days. Pricing takes place within 60 days maximum after which the complete registration dossier is submitted. Registration time varies according to whether the product is imported or local, and whether it is generic or innovative brand. (EDA- Registration, n.d.) Some key informants reported that the timeframe given in the decree is usually extended due to unclear requirements with regards to submitted documents in addition to rapidly changing registration rules and procedures.

Registration Committees:

The main committee responsible for registration is the Technical committee for medicines control. Pharmacy law 127 of 1955 specifies the committee composition as follows:

- The Undersecretary of the Minister for Pharmaceutical Affairs.
- A professor in one of the pharmacy schools.
- A professor in one of the medicine schools.
- A representative pharmacist from the Ministry of Health.
- The head of the National Organization for Drug Control & Research.
- Pharmacist from the pharmacists syndicate.
- Physician from the physicians syndicates.
- A representative from the committee of Egyptian pharmacopeia.
- A representative from Importers Union.
The law also specifies that the committee has the authority to approve or reject pharmaceutical products that it must provide justification for the rejection and that the decision should be taken in the presence of at least 7 members. There are many specialized and scientific committees that help the technical committee; their role is to assess and approve different parts in the registration dossier according to the type of the product (medicines, food supplements or biological products- generic or innovative brands). These committees are as follows:

- Pharmacology committee.
- Stability committee.
- Bioequivalence committee.
- Pricing committee.
- Specialized scientific committee for products with no reference.
- Scientific committee for biological products.
- Scientific committee for food supplements.

The selection criteria for committee members are not clear in the law or any publicly available ministerial decree. Internal written documents, usually ministerial decrees, describe the composition of these committees, but they are not published and even the names of the members are not known for industry persons. (Abd Elsalam, S.R., interview, April 6, 2011)
Registration workflow:

1. **Submission of 1st application**
   - Approval
   - Rejection

2. **Pricing**

3. **Submission of registration dossier**

4. **Studying by specialized & scientific committees**
   - Rejection

5. **Technical Committee Decision**
   - Rejection

6. **Market Authorization**
IV- Results in other countries:

This section introduces the results of the transparency assessments in the 14 countries mentioned earlier in this study, all data in this section is collected and paraphrased from the published reports about these assessments in the World Health Organization website.

**Transparency/vulnerability to corruption scores for all countries:**

The countries showed diversity on the scale of transparency/vulnerability to corruption (see table 8) from *moderately vulnerable* to corruption in Lao PDR, Syria, Cambodia, PNG and Malawi, *marginally vulnerable* in Malaysia, Philippine, Thailand, Indonesia, Mongolia, Jordan and Lebanon, and *minimally vulnerable* to corruption in Bolivia and Costa Rica.

In most of the countries registration score is relatively higher than other functions as it scores above the average of all functions together. Only in Lao PDR, Philippine, Thailand, Syria and Cambodia, registration function scored slightly below the average of all functions.
Table 8: Average scores of different countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Registration Score</th>
<th>Inspection Score</th>
<th>Promotion control Score</th>
<th>Selection Score</th>
<th>Procurement Score</th>
<th>Distribution Score</th>
<th>Average Score for all functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lao PDR1</td>
<td>5.6</td>
<td>__</td>
<td>__</td>
<td>6.1</td>
<td>6.7</td>
<td>__</td>
<td>6.13</td>
</tr>
<tr>
<td>Malaysia1</td>
<td>6.8</td>
<td>__</td>
<td>__</td>
<td>5.7</td>
<td>7.1</td>
<td>__</td>
<td>6.53</td>
</tr>
<tr>
<td>Philippines1</td>
<td>6.8</td>
<td>__</td>
<td>__</td>
<td>6.1</td>
<td>8.5</td>
<td>__</td>
<td>7.13</td>
</tr>
<tr>
<td>Thailand1</td>
<td>7</td>
<td>__</td>
<td>__</td>
<td>8.00</td>
<td>7.1</td>
<td>__</td>
<td>7.37</td>
</tr>
<tr>
<td>Syria1</td>
<td>5.12</td>
<td>5.88</td>
<td>4.47</td>
<td>5.67</td>
<td>6.3</td>
<td>__</td>
<td>5.49</td>
</tr>
<tr>
<td>Bolivia1</td>
<td>8.6</td>
<td>6.2</td>
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<td>__</td>
<td>6.66</td>
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<td>5.00</td>
<td>5.1</td>
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<td>5.4</td>
<td>__</td>
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<td>8.7</td>
<td>7.6</td>
<td>5.5</td>
<td>7.00</td>
<td>__</td>
<td>7.2</td>
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<td>7.8</td>
<td>4.4</td>
<td>5.9</td>
<td>6.2</td>
<td>__</td>
<td>6.1</td>
</tr>
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<td>PNG1</td>
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<td>2.6</td>
<td>1.7</td>
<td>4.5</td>
<td>6.6</td>
<td>__</td>
<td>3.94</td>
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<td>6.30</td>
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<td>__</td>
<td>3.03</td>
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<td>__</td>
<td>9.4</td>
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<td>6.02</td>
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<td>Egypt2</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1- Source: World Health Organization, different countries assessment reports.
2- Source: Author’s calculations
Brief results on quantitative indicator:

This section introduces brief about every single indicators as collected from WHO different countries assessment reports, see (table 8).

**Indicator 1, 2:** Having up-to-date list for registered products possesses minimum information (name, manufacturer, reg. date and expiration, package).

In all the countries except Papua New Guinea, there is a publicly accessible list for registered products that contains minimum information. In Syria, this list lacks important information such as registration date and validity. In Malawi, they have a database for the registered products but there was no evidence that an up-to-date list is available to the public.

**Indicator 3:** Having written publicly accessible procedures for applicants on how to apply for the registration process including time frame and fees.

All the countries have these written guidelines on how to submit the applications and needed documents; however, these guidelines are not implemented in PNG, do not mention timeframe and fees in Malawi and Syria. In Lebanon, mentioned timeframe is not binding due to queuing system.

**Indicator 4:** Having written publicly accessible procedures for assessors to assess applications.

Malawi, Bolivia, Mongolia and PNG have no written procedures for assessors to assess applications contents. Lebanon and Cambodia have only check list for the applications' contents with no detailed procedures. Remaining countries have such written procedures; however, it is not publicly accessible in Jordan.

**Indicator 5:** Having publicly accessible standard application form for submission to registration includes enough information.
Apart from PNG, all countries have publicly accessible standard application forms that contain enough information about the product being registered; however, it does not contain important information such as pharmacological action and contraindications.

**Indicator 6:** Written guidelines setting how and where registration officers meet with applicants.

Apart from Jordan, no county has such written guidelines on how and where applicants can meet registration officers during the process if they have inquiries or something missing. No information found about this indicator in Lao-PDR, Malaysia, Philippine, Thailand.

**Indicator 7, 8:** Formal committee selected by publicly accessible and written criteria specifying professional qualifications and skills.

Apart from PNG, all the countries have a committee or group of committees that is responsible for registration; however, there are large variations in having written or even well-known criteria for committee members' selection. In Jordan, written criteria are there for selecting the members of two of the registration committees; it specifies professional requirements, technical skills, experience in the area of expertise and identify a period for serving as a committee member. In Bolivia, there are written criteria covering all information however it is reported that these criteria are not usually respected. In Malawi, Malaysia, Thailand, Philippine and Lao PDR have some written criteria; however, they mainly identify members by positions having less detailed requirements. Remaining countries have no written criteria for selection of committee members.

**Indicator 9:** Having written updated publicly accessible document specifies composition and terms of reference of the committee; this should include members' names, responsibilities, accountability, rotation and financial benefits.
All countries have some sort of document that describes the committee composition; however, all of them are incomplete or unavailable for public. In Lebanon, it is available upon request.

**Indicator 10:** Having written guidelines on conflict of interest.

Indonesia is the only country that has a form for declaration of Conflict of Interest that should be filled by registration committee's members.

**Indicator 12:** Comprehensive written procedures for decision making.

This indicator also showed large variations among different countries, most of the countries have no written detailed procedures on decision making. Some countries reported that such procedures are well known by many years of practice such as Lebanon and Syria While others (e.g Bolivia) have written procedures but they are not publicly available. In Malaysia, it is reported that the decision should be taken by voting; however, key informants there reported that the process is not democratic enough as what is identified in the procedures.

**Indicator 13:** Formal appeal system for rejected applications.

All countries have formal appeal system for rejected applications except Cambodia, Syria, PNG and Lao PDR. In Lebanon, the appeal system is not independent as appeals are reassessed by the same committee.
## Table 9: Quantitative indicators

<table>
<thead>
<tr>
<th>Source/Condition</th>
<th>Lao- PDR</th>
<th>Malaysia</th>
<th>Philip-</th>
<th>Thai-</th>
<th>Syr-</th>
<th>Bol-</th>
<th>Camb-</th>
<th>Indo-</th>
<th>Mong-</th>
<th>PNG</th>
<th>Jordan</th>
<th>Mal-</th>
<th>Lebanon</th>
<th>Costa Rica</th>
<th>Egyp-</th>
</tr>
</thead>
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<td>Registration is a responsibility of MRA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Reg. products list contains (Name-description- company- reg. date)</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
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<td>✓</td>
</tr>
<tr>
<td>The list is publicly accessible</td>
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<td>✓</td>
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<td>✓</td>
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<td>✓</td>
</tr>
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<td>Written procedures for Applications submission- publicly accessible</td>
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</tr>
<tr>
<td>Written procedures to assess applications</td>
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<td>✓</td>
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<tr>
<td>Standard application form- publicly accessible and available</td>
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<td>✓</td>
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<td>✓</td>
</tr>
<tr>
<td>Contains: Name, summary of characteristics (pharmacological action, therapeu-</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>tic classification) and the packaging</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
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</tr>
<tr>
<td>Formally established committee composed of professionals</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Written guidelines &amp; mechanisms for decision making</td>
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</tr>
<tr>
<td>Provide official documents for all decisions explaining the reasons for rejec-</td>
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<td></td>
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<tr>
<td>Publicly available written document specify Committee's composition, term of re-</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td>fference.</td>
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<tr>
<td>A form for Conflict of interest</td>
<td></td>
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<td>Formal appeals system</td>
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</tr>
</tbody>
</table>
Perception Indicators:

**Indicator 11:** perceptions towards the statement "The members of the registration committee are systematically and objectively selected based on the written criteria in force in your country".

**Table 10: Perceptions toward the objectivity of committee's members selection in the 15 countries**

<table>
<thead>
<tr>
<th>Country</th>
<th>% KIs answered with &quot;agree&quot; and &quot;strongly agree&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lao PDR</td>
<td>___</td>
</tr>
<tr>
<td>Malaysia</td>
<td>___</td>
</tr>
<tr>
<td>Philippines</td>
<td>___</td>
</tr>
<tr>
<td>Thailand</td>
<td>___</td>
</tr>
<tr>
<td>Syria</td>
<td>36.84%</td>
</tr>
<tr>
<td>Bolivia</td>
<td>64%</td>
</tr>
<tr>
<td>Cambodia</td>
<td>33.3%</td>
</tr>
<tr>
<td>Indonesia</td>
<td>50%</td>
</tr>
<tr>
<td>Mongolia</td>
<td>20%</td>
</tr>
<tr>
<td>PNG</td>
<td>NA</td>
</tr>
<tr>
<td>Jordan</td>
<td>50%</td>
</tr>
<tr>
<td>Malawi</td>
<td>50%</td>
</tr>
<tr>
<td>Lebanon</td>
<td>50%</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>___</td>
</tr>
<tr>
<td>Egypt</td>
<td>26.7%</td>
</tr>
</tbody>
</table>

Source: WHO, different countries assessment reports.

*"agree" includes those who agree and strongly agree.

**Figure 4: Perception toward the objectivity of the committee's members selection**

Source: WHO, different countries assessment reports.
**Indicator 14:** perceptions towards the statement "benefits given to the officials in charge of medicines registration have no influence at all on the final decisions".

<table>
<thead>
<tr>
<th>Table 11: Perception toward the influences of benefits and gifts on the registration decisions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Country</strong></td>
</tr>
<tr>
<td>Lao PDR</td>
</tr>
<tr>
<td>Malaysia</td>
</tr>
<tr>
<td>Phillipine</td>
</tr>
<tr>
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<td>Cambodia</td>
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<tr>
<td>Indonesia</td>
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<tr>
<td>Mongolia</td>
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<tr>
<td>PNG</td>
</tr>
<tr>
<td>Jordan</td>
</tr>
<tr>
<td>Malawi</td>
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<tr>
<td>Lebanon</td>
</tr>
<tr>
<td>Costa Rica</td>
</tr>
<tr>
<td>Egypt</td>
</tr>
</tbody>
</table>

Source: WHO, different countries assessment reports.

*"agree" includes those who agree and strongly agree.

**Figure 5: Perception toward the influences of benefits and gifts on the registration decisions**

Source: WHO, different countries assessment reports.
Qualitative indicators:

**Indicator 16: The existence of unethical behaviors.**

Unethical behaviors that are reported by key informants in all countries are very similar. Favoritism, conflict of interest, discrimination, bribery and material gifts are the most frequently mentioned. No information is available regarding this indicator in Costa Rica, Lao PDR, Malaysia, Philippine or Thailand.

**Actions for improvement and recommendations drawn from various countries' reports:**

Based on the findings summarized above, several recommendations for improving performance in this area can be identified. These include:

1. **Improve management practices and reduce inefficiencies:**

   **Operation procedures:**
   
   - Improve the online registration information system.
   - Issue a "completeness letter" upon receiving the full application dossier, including a commitment to a timeframe from the registration authority for completion of the process, based on the date of this letter.
   - Develop an electronic submission system to receive registration applications.
   - Improve digital archiving of administrative and technical documents.
   - Institute a Comprehensive and systematic plan based upon in-depth study to resolve major problems and improve the registration system.
   - Comply with European guidelines regarding documents needed for registration.

   **Human resources:**
   
   - Integrate all medicines' regulatory functions and services in one body with new premises, equipments and staff and with a new system for incentives.
• Introduce of an up-to-date electronic knowledge management system to provide the latest information to staff.

• Put in place a recruitment system to hire qualified personnel.

• Increase the number of staff to speed up the process.

• Raise the qualifications of human resources are needed by improving the training and capacity building system in addition to creating an efficient salary and incentives systems.

2- Policy, regulatory and administrative reforms to improve transparency and accountability:

Registration policies and regulatory procedures need to be improved in order to achieve transparent and accountable system. This includes:

Registration policy and regulations:

• Articulate the country's policy towards the importance of bioequivalence studies, parallel import and patents, such that all decision areas are consistent with each others.

• Rotate Technical evaluators for new registrations.

• Institute a clear and comprehensive policy for herbal and natural medicines.

• Introduce better control on unregistered products in the market.

• Establish an independent appeals system.

• Educate public about the importance of registering medicines.

• Speed up the process of issuing important regulatory legislations that are needed in the pharmaceutical system.

• Study the country wide regulatory legislations and amendments by a committee of experts before issuing.
• Ensure the quality of unknown companies from which registered products are imported by inspecting them and issuing a qualified list of suppliers.

• Communicate all laws and regulations and make it available for public in an easy and effective way. Processes to enforce the laws should be clearly defined in addition to powers, roles and responsibilities of all officials, committees and regulatory bodies that are able to enforce the law.

• Communicate and disseminate all information, guidelines, procedures and decisions related to registration.

Registration committees:

• Written guidelines on the selection of committee members specify in details their professional and technical requirements.

• Consider scientific and ethical criteria while selecting committee members.

• Formal document specify committees' composition, mandates, terms of reference and accountability requirements.

• Develop written guidelines to registration committee work.

• Develop clear decree explain how decisions are made inside registration committee, make it publicly available, and enforce it in the decision making process.

• Develop and enforce guidelines on conflict of interest declaration by committees' members and all registration staff including penalties in case of undeclared conflict of interest.
Data Analysis

I- Transparency/vulnerability to corruption score and perceptions of KIs:

The registration function in the public pharmaceutical system receives an average transparency score of 5.04 on the 1 to 10 scale. This indicates moderate vulnerability to corruption. While 27% of the KIs believe that the committees' members are systematically and objectively selected (indicators 8 and 9), they also assigned low scores to the existence of clear and transparent selection criteria and procedures (0.08 and 0.25 respectively) indicating that rules and procedures are neither in place nor enforced. Similarly, 47% of the KIs believe that gifts and benefits have no influence at all on the committee decisions, but assigned a score of 0.09 to the relevant indicator (10, which assesses the existence of guidelines on the declaration of conflict of interest. This means that there are no clear rules and procedures in place to prevent conflict of interest. Moreover, this reflects a large gap in regulations and procedures that needs to be addressed in order to improve governance in the sector.

II- Strengths and weaknesses in the registration process in Egypt with regard to transparency and accountability:

According to the results above, some strengths and weaknesses need to be addressed for further improvement.

The strengths include:

- There is an up-to-date list for all registered medicines available on the website of the EDA and it contains sufficient information related to every product. The last update was on February 24, 2011. In addition, lists for biological products and food supplements are available.
- Detailed written procedures for applicants are available on the website; however, the information needs some extra efforts to keep it updated because some KIs reported that these procedures change without regular notifications.

- The EDA website is very informative and contains plenty of resource documents that describe activities, procedures, decrees and decisions; however, it needs to be more organized so that the data can be easily found.

- There are a standard application forms for registration and pricing respectively and they are available on the website for all applicants.

The weaknesses include:

- There are no clear criteria for selection of either technical committee members or other scientific sub committees' members who help in assessing the registration dossier. Although the law specifies that the committees should include representatives from certain bodies, it does not set criteria for selection. All the interviewees from the public sector mentioned that there are no criteria for selection and that the committees' members are selected by the senior officials and then listed in ministerial decrees.

- There are no written guidelines on conflict of interest with regard to registration activities. In addition, some interviewed public officials mentioned some practices that showed conflict of interests do occur within committee work.

- The written documents that specify the committees' composition are not published, even internally. No one has access to them except senior management officers. Interviewees mentioned that the documents specify only the names with no terms of references, accountability requirements, rotation guidelines or financial benefits for members.
• No clear guidelines or procedures govern decision making inside the committees. Some interviewees mentioned that there are no rules for assessing the registration dossier. They reported discretionary practices by some members. Some members may dominate and enforce their opinions while others are not satisfied as reported by some KIs.

• Although the regulation calls for an independent appeal committee that can reassesses the rejected applications, this regulation needs to be enforced because most of key informants reported that the technical committee itself is the entity that reassesses these appeals.

• The regulatory framework for registration has changed many times in the last few years while some regulations are not consistent with each others. Some regulations are not well enforced while others are retroactively implemented. This situation underlies the reports of many inefficiencies and opaqueness by industry KIs.
III- Comparative Analysis:

This section analyzes the results in the 14 developing countries comparing them with those of Egypt, common themes and a number of useful experiences in the comparator countries will be identified.

Transparency/vulnerability to corruption score:

Egypt's score is one of the lowest as it scored below the average score of the other 14 countries. In the region, Syria has almost the same score as Egypt and both are moderately vulnerable to corruption. Jordan and Lebanon have higher scores as their systems rank as marginally vulnerable to corruption. One of the main reasons behind Egypt's relatively low scores is because it suffers from weaknesses in both of categories, that is a weak regulatory and procedural framework and weakness in the management system needed to enforce and monitor the rules and regulations. This is addressed in detail in the next section.

Common weaknesses and problems:

Reviewing types of problems with regard to governance in all of the 15 countries including Egypt, we can see two main categories of weak points in the registration system. First, these countries lack clear and comprehensive regulatory frameworks and procedures to organize the process. As a result, they cannot ensure full transparency and accountability of all staff and committees members, as shown in examples provided earlier showing absent or unclear rules and regulations. Second, they have weak and inefficient management systems that fail to enforce regulations and implement rules and procedures or do so in an inefficient way.
First category: Lack of clear and comprehensive regulations and procedures for registration activities:

Weaknesses under this category relate to the regulatory framework and rules that organize, influence and guide the registration decisions. These include the registration committees' composition, the mechanisms of decision making and policies that regulate conflict of interests. These weaknesses need interventions to introduce new regulations or amend those in place currently to be more comprehensive and consistent with each other. Strong and efficient management systems are needed to enforce and monitor these new regulations. This category includes:

- Detailed criteria are lacking for the selection of the committees members to describe the required professional qualifications, skills and experience, and specify fixed and non-renewable period of service.
- The decree that nominates committees members usually lacks terms of references, responsibilities and accountability requirements, and is not publicly available.
- No policy exists to regulate the declaration of conflict of interests for the registration committees members.
- Written guidelines are lacking to regulate the process of decision making inside the committees, meeting minutes are not publicly available. Opaque and discriminatory practices were reported due to poor and sometimes contradictory regulations for decision making.
- Clear written guidelines are lacking for the appeal system. Sometimes the appeal system is not totally independent as the same committee who rejected the application also reviews appeals.
Second Category: Weak management systems to enforce regulations:

Weak points under this category are related to inefficient management practices that are inadequate to enforce regulations and procedures such as inexperienced personnel that assess files, poor supervision and accountability systems and inefficient incentives systems. The weaknesses in this category include:

- Complete written procedures are lacking such that registration officers have insufficient guidance on how to assess the application documents. Procedures do not specify in detail the steps to follow, the timeframe for processing, whether special issues should be considered, how to write reports, or procedures to hold members accountable according to these procedures and timeframe.

- No official written documents are required from the committee for each decision regarding the application.

- Some of the staffs who work in the registration department lack proper technical and soft skills.

- The Archiving system functions poorly.

- There is a lack of mechanisms to update information and procedures and communicate it efficiently and immediately with no delays such as information about the registered products in the market and the changes in registration procedures.

- Detailed written guidelines for applicants on the steps to submit applications are lacking or do not specify documents are needed, fees and the strict timeframe for processing. In addition, sometimes clear disseminated information on how and where applicants can meet responsible officials is not provided.
Countries in both categories:

The countries that have problems in the first category one usually have problems in the second category as well. Those countries include Syria, Cambodia, Mongolia, Papua New Guinea and Egypt. In these countries we can see inadequate regulation and procedure in addition to poor management and monitoring practices. The remaining countries suffer mostly from the problems in the second category to varying degrees. For example in Bolivia, there are written criteria for the selection of committee's members; however, it was reported that these criteria are not used in the selection. In Malaysia, despite the presence of written procedures for the decision making mechanism, it was reported that the voting system inside the committee is not enforced and the decisions are not very democratic.

The Egyptian case experiences both types of problems. Interventions are needed to decrease management inefficiencies, reform the registration regulatory framework and improve transparency as well.

A final word about countries' ratings for transparency in other functions:

In most of the countries, the registration score is relatively higher than other functions on average. Only in Lao PDR, Philippines, Thailand, Syria and Cambodia does the registration function scored slightly below the average of all functions. The area with the lowest scores is typically control over medicine promotions and advertising. In general, the same pattern of regulatory and procedural weaknesses and poor management can be seen in the other areas. Thus, the main themes and guidelines in the framework for improvement in registration function in Egypt could be expected to be generalizable to other areas in the pharmaceutical system, taking into consideration specific technical details in each area.
IV- Correlation between the scores of public pharmaceutical sector and the corruption perceptions index of the whole country:

In this section, I test the correlation between the degree of vulnerability to corruption in the pharmaceutical sector and the corruption perceptions index (2010) for the whole country. The corruption perceptions index is calculated by Transparency International using data from experts and analysts from the African Development Bank, Asian Development Bank, Bertelsmann Foundation, Economist Intelligence Unit, Freedom House, Global Insight and the World Bank, in addition to data from the countries’ business leaders, and evaluations such as IMD, Political and Economic Risk Consultancy, and the World Economic Forum (Transparency International [TI], n.d. Short methodology).

The results shown in Tables 12.1 and 12.2 demonstrate significant correlation (0.619) between the two variables. This suggests the importance of the actions taken on the national level in any plan aimed to improve governance in the pharmaceutical system in the country. One of the countries studied, Jordan uses this approach. Implementation of legal reforms to combat corruption and strong monitoring and supervision systems were a critical part in the design of their framework to combat corruption (WHO, n.d.).
Table 12.1: Vulnerability to corruption in pharmaceutical sector and corruption perceptions index

<table>
<thead>
<tr>
<th>Country</th>
<th>Transparency score in public ph. sector (registration)</th>
<th>Corruption perceptions index</th>
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<tbody>
<tr>
<td>PNG</td>
<td>4.3</td>
<td>2.1</td>
</tr>
<tr>
<td>Malawi</td>
<td>4.84</td>
<td>3.4</td>
</tr>
<tr>
<td>Egypt</td>
<td>5.04</td>
<td>3.1</td>
</tr>
<tr>
<td>Cambodia</td>
<td>5.1</td>
<td>2.1</td>
</tr>
<tr>
<td>Syria</td>
<td>5.12</td>
<td>2.5</td>
</tr>
<tr>
<td>Lao PDR</td>
<td>5.6</td>
<td>2.1</td>
</tr>
<tr>
<td>Mongolia</td>
<td>6.2</td>
<td>2.7</td>
</tr>
<tr>
<td>Lebanon</td>
<td>6.52</td>
<td>2.5</td>
</tr>
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<td>6.8</td>
<td>4.4</td>
</tr>
<tr>
<td>Philippines</td>
<td>6.8</td>
<td>2.4</td>
</tr>
<tr>
<td>Thailand</td>
<td>7</td>
<td>3.5</td>
</tr>
<tr>
<td>Indonesia</td>
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</tr>
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<td>Jordan</td>
<td>7.52</td>
<td>4.7</td>
</tr>
<tr>
<td>Bolivia</td>
<td>8.6</td>
<td>2.8</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>9.4</td>
<td>5.3</td>
</tr>
</tbody>
</table>

1- Source: WHO, different countries reports.
2- Transparency International: Corruption perceptions index 2010

Table 12.2: Correlation results

<table>
<thead>
<tr>
<th>Correlations</th>
<th>VAR000001</th>
<th>VAR000002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ph. sector</td>
<td>Pearson Correlation</td>
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</tr>
<tr>
<td>vulnerability to corruption score</td>
<td>Sig. (2-tailed)</td>
<td>.014</td>
</tr>
<tr>
<td>Perception</td>
<td>Pearson Correlation</td>
<td>.619*</td>
</tr>
<tr>
<td>corruption index</td>
<td>Sig. (2-tailed)</td>
<td>.014</td>
</tr>
<tr>
<td>N</td>
<td>15</td>
<td>15</td>
</tr>
</tbody>
</table>

* Correlation is significant at the 0.05 level (2-tailed).

Source: Author's calculations
**Discussion and recommendations: framework for improvement**

In the last few years, Egypt made important efforts to strengthen medicines regulatory and management systems, especially with regard to medicine registration. Registration procedures were integrated in one office in a trial to introduce a one-stop-shop for companies to process all procedure related to registration. A new ministerial decree was issued to regulate and organize the registration process setting a timeframe for each step. A new website was established containing all information and forms needed for registration and other activities in the Egyptian regulatory authority.

Despite these steps toward good governance practices; important steps still were missed, according to the key informants. This study has provided an assessment of the degree of transparency in the sector. It aimed to sound the alarm about the weak points that could be vulnerable to corruption if measures to improve transparency and accountability are not introduced as soon as possible.

The key informants reported problems related to opaqueness of the procedures of the registration process especially those related to the registration committees. The selection criteria of the members, committees' composition and responsibilities and the mechanisms of decision making are the most opaque elements, in addition to the lack of any measures for accountability and conflict of interest. Moreover, some other problems are reported with regard to inefficiency and incompetence, such as the lack of detailed procedures and guidelines for assessors and committee members, inexperienced assessors, inefficient incentives systems, violated timeframe, miscommunication, contradictory and highly changeable regulations, and issuance of new regulations without taking enough time for study.

According to Cohen, Mrazek & Hawkins (2007), it is problematic to
differentiate between corruption, inefficiencies and incompetence. Inefficiencies and incompetent management practices could also foster corruption. This is why the framework for making improvement towards good governance and prohibiting corruption in the Egyptian pharmaceutical system should address these inefficiencies in addition to transparency and anticorruption measures. When the key informants were asked about the improvements they would like to introduce to the registration process, their responses confirmed the importance of addressing regulatory and administrative inefficiencies. The most frequent answers were related to inefficiency. Thus, combating corruption needs firstly strong anti-corruption legislations, but clear and transparent regulations and procedures should also be there to decrease discretionary power. Legislations and regulations should be effectively enforced via strong and efficient management and supervision systems. Such a framework could be applied to the whole pharmaceutical system as experience in other countries has shown that there tend to be similar weaknesses across all functions.

**Proposed framework for improvement:**

1. **Formulation of clear regulations, rules and procedures:**

   Clear and transparent rules and procedures decrease discretionary practices by public officials on one hand (WHO, 1999, March 16), and hold public officials accountable on the other. This includes the following:

   - Reviewing all regulations related to registration process and then integrating them in a comprehensive consistent code of regulations to eliminate contradictions and instability of the current regulations.
Developing clear written procedures and steps to be followed by applicants to apply for registration including all needed data and documents in addition to binding timeframe and fees.

Setting out clear, written and detailed procedures for assessors in the registration department on how to assess files.

Instituting clear written criteria for selections for all committees' members.

Providing clear written responsibilities, terms of references, mechanisms of rotation of all committees' members and registration staff.

Putting in place clear written guidelines on the declaration of conflict of interests.

Establishing clear and documented mechanism for decision making inside the committee that is democratic, efficient and documented in the published minutes.

These rules and procedures should be fully transparent and widely disseminated internally and externally. Participation of important stakeholders groups (public officers, companies, professional associations, patient groups, etc.) will create agreement and acceptance and therefore facilitate implementation.

Efficient management and supervision system:

Effective drug regulations should be enforced and interpreted to guide actions through efficient management systems that create a suitable organization structure, allocate adequate resources (WHO, 1999, March 16) and evaluate performance. In the Egyptian context, this should include the following:

- Recruiting highly qualified staff and offering them proper and adequate training before assignment of important tasks and responsibilities. This implies a need for an efficient, reformed, and institutionalized system for recruiting and
Training should include soft skills and technical skills in pharmaceutical industry.

- Clarifying the distribution of roles and responsibilities of staff and committee members and mechanisms to hold them accountable.
- Establishing an incentives and rewards system based on performance appraisal by customers as well as managers.
- Clarifying functional and structural linkages among different committees and units, identifying work flows and publishing this information for all applicants so they can follow up on their applications.
- Studying the applicability and feasibility of introducing electronic submission of registration dossiers to facilitate the process and decrease the contact points between staff and clients.
- Introducing a digital archiving system.
- Establishing an independent system for reporting complaints, taking actions and adopting recommendations for improvement.
- Using an external financial auditing body for regular evaluation of the efficiency of resource allocations.

There are many difficulties that will delay the introduction of such reform in administrative structure by the EDA as long as it operates under the control of the Ministry of Health. The establishment of a new autonomous regulatory body for medicines is one of the best solutions. The performance of medicine regulation in Jordan and Saudi Arabia showed great improvement after the establishment of the Jordan Food and Drug Administration and the Saudi Food and Drug Authority, respectively. The nature of the pharmaceutical sector in both countries is different from Egypt's case; for example, the Jordanian pharmaceutical market is much
smaller than the Egyptian (BMI, 2009a) and Saudi Arabia imports about 85% of the pharmaceutical consumption (Saudi Food and Drug Authority [SFDA], 2008) while Egypt has huge and highly diversified pharmaceutical market. However, it will be useful to study the feasibility and applicability in the Egyptian context while considering the successes and lessons learnt in similar experiences in the region.

2. Framework to combat corruption in pharmaceutical system:

The WHO provides a framework for an integrity system in the pharmaceutical system, the "national integrity system," incorporating the key elements promoted by Transparency international: leadership, public programmes, government reorganization, law enforcement, public awareness and the creation of institutions to prevent corruption. This “framework for integrity system” is based on two approaches: 1) the discipline approach which is top-down based on anti-corruption legislative and administrative reform for laws, regulations and procedures that combat corruption, and 2) the value approach which is bottom-up, based upon building consensus on an ethical and moral framework via the participation of all key actors and public servants to create ownership and motivation to adhere to ethical values and norms. In accordance with WHO’s proposed integrity system (WHO, 2008a), the Egyptian public pharmaceutical system should:

- Initiate the establishment of an ethical and moral system.
- Develop a code of conduct which is best achieved by a participatory mechanism rather than a top-down approach to create ownership and promote adherence.
- Establish a program to promote and socialize participants in ethical principles, values, codes of conduct and moral leadership.
• Establish management procedures that promote integrity values, enforce regulations, and regularly evaluate the integrity system.

On the national level, anti-corruption legal reform should be strengthened in Egypt, Maged (2010) proposes a framework for legal reform drawing upon international standards and tailoring it to fit the Egyptian context. The main components he recommends are:

• Criminalization of specific acts of corruption: Although the Egyptian Penal Code No. 58/1937 and its amendments address a wide range of corruption practices, specific forms and actions are not identified in details such as abuse of authority and making use of office for personal gains, these practices are not considered criminal conduct.

• Freedom of information law: This law should regulate the administrative procedures that allow the public access to decision making processes and information. According to the United Nation Convention Against Corruption (UNCAC), people should be able to monitor the public servants conduct. Consequently, disclosure and freedom of information should be ensured by law. Maged (2010) reported that the Egyptian government has considered issuing this law; this will may be strengthened after the revolution. With regard to the pharmaceutical public sector specifically, more efforts are needed to enforce the law and organize the management of information.

The experience of the FDA Transparency Initiative could also offer guidance in this context. In 2009, after the issuance of the "Open Government Directive" that forced government bodies in the U.S. to implement the principles of transparent, collaborative, and participatory government via certain actions, the U.S. FDA
launched its own initiative through the formation of a Task Force to implement these directives in the FDA context. The initiative consists of three phases;

- Phase 1 provides basic information about FDA and its work to the public.
- Phase 2 acts on the disclosure of information about FDA’s activities and decision making process.
- Phase 3 studies the ways to be more transparent to industry and to improve efficiency and cost-effectiveness of the regulatory process.

The FDA conducts the three phases via a participatory process through which they hold meetings and seminars with stakeholders in each phase, issue a draft proposal for policy changes needed in each phase, receive comments from stakeholders, study the comments and proposals with regard to their feasibility and priority, and then make final recommendations for policy changes. (FDA, n.d.)

- Legislations to protect whistle-blowers: People who report corrupt practices should be protected from being intimidated or retaliated against. According to UNCAC, anonymity of witnesses and whistle-blowers should be preserved and intimidation and retaliation should be criminalized.

- Code of conduct: Good practice standards for public servants should be identified, ethical and moral values should be very well known by them and mechanisms for holding them accountable to these standards should be identified.

- Strengthening and enforcement of the monitoring and supervision systems: There are a number of governmental agencies that investigate corruption practices. These agencies are:

  - Administrative Prosecution Authority.
  - Administrative Control Authority.
- Central Auditing Authority.
- Illicit Enrichment Apparatus.
- Public Fiscal Prosecution Authority at the Office of the Prosecutor General.

However; an independent body is needed to focus on the prevention of corruption via proper prevention strategies national wide.

After the revolution, the new government showed commitment to more transparent and participatory decision making process. Applying the previous framework in this context implies many benefits to the pharmaceutical sector. This includes comprehensive regulatory framework, strong integrity system and efficient management practices that will push the sector forward toward the accomplishment of its mission. Consequently, this will maximize the country wide health outcomes.
References:


Annex 1

Important definitions

National Medicines Regulatory Authority/ National Drug Authority

The primary responsibility of the MRA is to operate a system of administration and enforcement intended to ensure that all medical products subject to its control conform to acceptable standards of quality, safety and efficacy; the promotion and marketing of medicinal products is in accordance with approved product information; the use of medicines is rational, and that all personnel, premises and practices employed to manufacture, store distribute and sell, supply and dispense these products comply with requirements to ensure the continued conformity of the products with these standards until they reach the final user/consumer. Usually MRA performs important functions such as strategic planning and policy making for the pharmaceutical sector, regulating and supervising pharmacy practice in hospitals, community pharmacies, and industry and distribution facilities, releasing market authorization for all pharmaceutical products in the market. (WHO, 2009a)

Pharmaceutical System

Pharmaceutical system refers to the relationship/interactions between the various actors of the pharmaceutical sector and the way decisions are made in particular in the government. (WHO, 2009a)

Pharmaceutical Policy

Pharmaceutical Policy is the set of principles that guide the government's decision making and regulations with regard to medicine manufacture, distribution, prescribing and use.

Pharmaceutical sector

Refers to the various actors involved in the area, namely the government, private for profit organizations, private not for profit organizations, etc., engaged in the research, manufacture, import, export, distribution, retail, etc. of medicines. (WHO, 2009a)

Medicine registration (Market authorization or product licensing)

The procedures to evaluate safety, efficacy and quality of the pharmaceutical products before authorizing it to enter the market; only medicines that pass through this step successfully are allowed to enter the market. (WHO, 2009a)

Licensing

Licensing of pharmaceutical establishments is a regulatory activity through which the (MRA) ensure that premises employed to manufacture, store, distribute and sell, supply and dispense pharmaceutical products comply with requirements set by standards and regulations in the country. All previous premises should apply for licensing by the MRA in order to obtain an approval (license) to operate in the country. (WHO, 2009a)
**Inspection**

The inspection of medicine manufacturers, importers, wholesalers, retailers, etc (pharmaceutical establishments) is an essential function of a medicine regulatory authority. The purpose of inspection is to ensure that pharmaceutical operations, such as production, import, export, distribution and promotion, are carried out in accordance with the approved norms, standards and guidelines and with the national medicines legislation and regulations as well. Its goal is to ensure that medicines used by the population are safe, efficacious, and of good quality. (WHO, 2009a)

**Medicine promotions**

Information about medicines designed to inform patients and health professionals about the medicinal products; it could be in different forms such as product labeling, package insert — patient information leaflet, journals, review articles, bibliographic indexes and other published materials, reference books, textbooks, formularies, standard treatment guidelines, medicine compendia, medicine bulletins, manufacturers’ promotion materials, On line advertising. Regulating medicine information and promotion is therefore necessary to prevent the dissemination of inaccurate and misleading information and ensure access to unbiased, truthful medicine information to enhance appropriate use of medicines by healthcare providers and patients. (WHO, 2009a)

**Essential medicines**

Essential drugs are the group of medicines that satisfy the primary health care needs of the population in a certain country. WHO recommends that "essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford." (WHO definition)

**(ICH) The International Conference on Harmonization**

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is an initiative to bring together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has evolved, through its ICH Global Cooperation Group, to respond to the increasingly global face of drug development, so that the benefits of international harmonization for better global health can be realized worldwide. ICH's mission is to achieve greater harmonization to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. (ICH, n.d)
Annex 2

QUESTIONNAIRE ON REGISTRATION OF MEDICINES

(Copied from WHO transparency measuring instrument)

PRELIMINARY INFORMATION

Date: _______________________

Key informant number: __________

The key informant works in:

- Government (public sector)
- Private sector
- Nongovernmental organization
- International governmental organization
- Media
- Other (please specify): __________

I.1 Is there an up-to-date list of all registered pharmaceutical products available in the country?

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

I.2 If such a list exists, does it provide a minimum level of information?

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Product description: name of product</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2. Primary packaging any identifying mark</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>3. Name of manufacturer</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>4. Country of manufacture</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>5. Site of manufacture</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>6. Date of registration</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>7. Validity of registration</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>8. Conditions for registration (ex Prescription only or OTC)</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### I.3 Are there written procedures for applicants on how to submit an application for registration of medicinal products? If so, are these procedures:

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
<th>Yes</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Written procedures</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2.</td>
<td>Publicly accessible</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>3.</td>
<td>Describe the process to follow in submitting an application?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>4.</td>
<td>Mention timeframe for processing</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5.</td>
<td>Mention fees</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6.</td>
<td>Mention data to be submitted</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>7.</td>
<td>Mention criteria for registration</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

### I.4 Are there written procedures for assessors on how to assess applications submitted for registration of medicinal products? If so:

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
<th>Yes</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Written procedures</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2.</td>
<td>Publicly accessible</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>3.</td>
<td>Describe the process to follow in submitting an application</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>4.</td>
<td>Mention timeframe for processing</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5.</td>
<td>Specify issues to be considered in assessing submissions</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6.</td>
<td>Provide guidance on report writing</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>
Total yes

Total valid answers

Scoring

(total yes/total valid answers)

I.5 Is there a standard application form publicly available for submission of applications for registration of medicinal products? If so:

<table>
<thead>
<tr>
<th>Description</th>
<th>No</th>
<th>Yes</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Publicly accessible</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2. Readily available at government office</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>3. Requires description of the product: name of product (brand name &amp; INN), composition per unit, dose</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>4. Brief summary of method of manufacture</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>5. Specification of pharmaceutical ingredients and excipients</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>6. Summary Product Characteristics (SPC): Pharmacological action, therapeutic classification, indications, contraindications, etc.</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>7. Packaging material and inserts</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>8. Labelling</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total yes

Total valid answers

Scoring

(total yes/total valid answers)

I.6 Are there written guidelines setting limits on how and where medicines registration officers meet with applicants?

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
I.7 Is there a functioning formal committee responsible for assessing applications for registration of pharmaceutical products?

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

I.8 Are there clear written criteria for selecting the members of the committee?

If so:

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Written criteria</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2. Criteria publicly available</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>3. Specify professional qualification required</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>4. Specify the technical skills and work experience related to the area</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>5. Require declaration of conflict of interest (e.g. investment in pharmaceutical business)</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>6. Give a timeframe to serve as a committee member</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

*Total yes*

*Total valid answers*

*Scoring*

*(total yes/total valid answers)*

I.9 Is there a written document that describes the composition and terms of reference of the committee? If so:

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Up-to-date document</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2. Publicly accessible</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>3. Includes names of the members</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>4. Includes duties, responsibilities and obligations of the members</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>5. Includes the accountability of the members</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>6. Includes quorum requirement</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>7. Includes membership terms/rotation requirements</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>8. Includes the financial benefits of the members, if any</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
I.10 Are there written guidelines on conflict of interest (COI) with regard to registration activities? If so:

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
<th>D.K.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Guidelines on COI exist in writing</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2. Form for declaration of COI for members of registration committee exists</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>3. Include rules on the acceptance of gifts</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>4. Include rules on reporting conflict of interest</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>5. Include a mechanism protecting informers of COI</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>6. Include actions to be taken in case of failure to comply with policy</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>7. Evidence of enforcement of these regulations</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

I.11 To what extent do you agree with the following statement: "The members of the registration committee are systematically and objectively selected based on the written criteria in force in your country"? (see question 8)

I.12 Are there clear and comprehensive guidelines for the committee's decision-making process? If so:
1. Available in writing
   No  Yes  D.K.
   0   1
2. Available publicly
   No  Yes  D.K.
   0   1
3. Describe clearly the mandate of the committee
   No  Yes  D.K.
   0   1
4. Describe the number of meetings it should convene
   No  Yes  D.K.
   0   1
5. Describe procedures for decision-making
   No  Yes  D.K.
   0   1
6. Include clear time limits for decision-making process for the committee
   No  Yes  D.K.
   0   1
7. Describe the reporting structure
   No  Yes  D.K.
   0   1
8. Decisions of meetings need to be publicly available
   No  Yes  D.K.
   0   1
Total

Total yes

Total valid answers

Scoring

(totals yes/total valid answers)

I.13 Is there a formal appeals system for applicants who have their medicine applications rejected?

No  Yes
0   1

I.14 To what extent do you agree with the following statement: "Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on the final decisions"?

Strongly Disagree  Disagree  Undecided  Agree  Strongly Agree  N.A.  D.K.

I.15 To what extent do you agree with the following statement: "The registration committee meets on a regular basis and keeps minutes for its meetings"?

Strongly Disagree  Disagree  Undecided  Agree  Strongly Agree  N.A.  D.K.
I.16 In your opinion, what types of unethical behaviour are common in the registration system in your country?

I.17 If you were in a position of highest authority, what would be the first action that you would take to improve the registration process in your country?
Annex 3

Comments on each indicator

(Copied from WHO transparency measuring instrument)

Indicator I.1:

*Is there an up-to-date list of all registered pharmaceutical products available in the country?*

**Rationale:** An official and up-to-date list of all registered pharmaceutical products containing accurate and current information can help to indicate how transparent the medicine registration system is about the pharmaceutical products authorized to circulate in the market. It will also ensure that medicines rejected in other countries for safety or efficacy reasons, medicines registered in one country and not yet in other, and medicines produced by manufacturers noncompliant with Good Manufacturing Practices (GMP) are not registered. Thus it also measures the degree to which a government protects its population from low-quality, unsafe and ineffective products. Making the list easily accessible to the public and all stakeholders will help them identify which product is legally approved and which one is illegally sold.

**Description:** There should be an easily accessible, official, up-to-date list of pharmaceutical products approved for sale or distribution in the country. Medicines not on the official list should be considered non-approved and should not be available in the market for sale or use. Medicine registration must be based on an objective assessment of a medicine’s efficacy, safety, quality and the accuracy of the information in the product packaging. The indicator is applicable to all pharmaceutical products mentioned in the national legislation as requiring registration.
**Interpretation guidelines:** If an up-to-date and official list of all registered pharmaceutical products exists, then the indicator will be rated with a 1. If it does not exist or it has not been updated then the indicator will be rated with a 0. If this list is in the process of being developed or updated, the indicator will also be rated with a 0.

**Indicator I.2:**

*If such a list exists, does it provide a minimum level of information?*

**Rationale:** The list of all pharmaceutical products officially registered in a country should provide a certain level of information as a minimum. This will indicate how transparent the government is in terms of the information obtained for each product. It will also indicate how systematic it is in getting the same information from all companies, and whether any exceptions are made as a result of gifts or any other benefits. Additionally, the availability of such information helps health workers, pharmacists, dispensers and patients to find out if a product is registered with the authorities and what the conditions for registration are.

**Description:** The list should provide sufficient and accurate information, and include:

– the description of the product including the name of the product;

– packaging and any identifying mark;

– country of manufacture;

– site of the manufacturer;

– the date of registration;

– validity of registration;
the conditions for registration, for example whether the medicine is prescription-only or can be bought over-the-counter (OTC).6

**Interpretation guidelines:** If there is no evidence of such a list then the indicator will be rated with a 0. If the list exists, rate the indicator as a *Method 2* question.

**Indicator I.3:**

*Are there written procedures for applicants on how to submit an application for registration of medicinal products?*

**Brief description of the indicator:**

Detailed written procedures for applicants should be easily accessible on how to register a product. This ensures the objectivity of the process in addition to

**Rationale:** Consistent and open procedures for medicine registration for all applicants (e.g. manufacturers, importers) are critical for a transparent pharmaceutical system. This ensures that decision-making is based on objective criteria and is not just subjective. It will also ensure consistency and avoid confusion in communications between applicants and registration staff (as everyone will use the same terminology).

**Description:** The written procedures must:

– be available in writing;
– be clear and publicly accessible;
– describe comprehensively and cogently the processes to follow in submitting an application;
– specify the data to be submitted;
– give the timeframe for processing an application;
– specify the fees; and
– the criteria for medicine registration. There should be no ad hoc exceptions to the standard requirements.

**Interpretation guidelines**: If there is no evidence of such a procedure then the indicator will be rated with a 0. If the procedure exists, rate the indicator as a *Method 2* question.

**Indicator I.4:**

*Are there written procedures for assessors on how to assess applications submitted for registration of medicinal products?*

**Rationale**: As with the applicants, assessors will need to follow clear procedures on how to assess an application submitted for registration to ensure that decision making is based on objective criteria and is not subjective.

**Description**: Procedures should:

– be available in writing;
– be publicly accessible;
– describe the process to follow in assessing submissions;
– give the timeframe for processing an application;
– specify the issues to be considered in assessing submissions; and
– provide guidance on report writing.

**Interpretation guidelines**: If there is no evidence of such a procedure then the indicator will be rated with a 0. If the procedure exists, rate the indicator as a *Method 2* question.

**Indicator I.5:**

*Is there a standard application form publicly available for submission of applications for registration of medicinal products?*
Rationale: A standard application form is a tool for ensuring consistent registration practices for all applications. It helps to ensure that medicine products are evaluated on objective criteria and that these are applied uniformly, irrespective of the supplier or manufacturer. This is important to foster fair market access.

Description: The document should:

– be publicly accessible;
– be readily available in the government office;
– as a minimum require a description of the product, such as the name of the product (brand name and INN) and the composition per unit dose;
– include a brief summary of the manufacturing method;
– include the specifications of active ingredients and excipients;
– give the Summary Product Characteristics (SPC), including the pharmacological action, therapeutic classification, indications and contraindications;
– give details of the packaging material; and
– details of labeling.

Interpretation guidelines: If there is no evidence of an application form then the indicator will be rated with a 0. If the application form exists, rate the indicator as a Method 2 question.

Indicator I.6:

Are there written guidelines setting limits on how and where medicines registration officers meet with applicants?

Rationale: Meetings between the medicines regulatory authorities and applicants can be helpful for both parties as they can clarify issues or misunderstandings. Requests for such meetings should be submitted to the Medicine Regulatory Authority (MRA) and/or registration division in writing, indicating the purpose and
who will attend on the applicant's side. The MRA must maintain control over the venue, conduct and content of the meeting. For example, it is useful to have more than one MRA staff member present to avoid any real or perceived conflict of interest in the outcomes of the meetings. Also the minutes of the meetings need to include the names of those who attended, from both the applicant and MRA's sides.

**Description:** Such a document should be obtained from the MRAs and MRA staff, applicants and other interested parties should be familiar with it.

**Interpretation guidelines:** If such a document exists and the KI knows about it then the indicator should be rated with a 1. If it does not exist then the indicator will receive a 0. This document may exist but the KI is unaware of it (in which case it will be rated 0), or the guidelines included may not be systematically applied. In such cases more explanation should be provided in the text of the report.

**Indicator I.7:**

*Is there a functioning formal committee involved in the assessment of the applications for registration of pharmaceutical products?*

**Rationale:** The presence of a formal committee with carefully selected members who will assess applications helps to ensure that evaluations of dossiers are carefully examined and assessed, and that the system is participatory and transparent. Such assessments should not depend on the judgment of a single person, as is the case in some countries.

**Description:** This committee should be composed of experts, not of political appointees. This committee should be impartial and ensure that the applications submitted for registration are assessed for efficacy, safety, quality, accuracy and completeness of product information.
**Interpretation guidelines:** If the committee is formally established and is operational, then this indicator should be rated 1. If the committee exists but is not operational, then this indicator should be rated 0. If committee formation is not formalized, then this indicator should receive a 0.

**Indicator I.8:**

*Are there clear written criteria for selecting the members of the committee?*

**Rationale:** Members of the committee should be selected on the basis of clearly written criteria to ensure that selection is done solely on the grounds of professional expertise, and is free of conflict of interest and favouritism. This will help to ensure that decisions for approving or rejecting a registration application for a product are based on scientific and independent grounds, leading to the circulation of safe, quality assured and efficacious medicines on the market.

**Description:** Criteria for selecting the members of the committee should:

– be available in writing;
– be publicly available;
– define the professional qualifications required;
– define the necessary technical skill and work experience of the experts to be selected;
– require that all members declare any real or perceived conflict of interest (e.g. investment in a pharmaceutical company, spouse working in a pharmaceutical company, payment received from companies or individuals, etc.);
– specify the timeframe to serve as a committee member.

**Interpretation guidelines:** If there is no evidence of such a criteria then the indicator will be rated with a 0. If the criteria exists, rate the indicator as a *Method 2* question.
Indicator I.9:

*Is there a written document that describes the composition and terms of reference of the committee?*

**Rationale:** A written document that describes the committee membership, roles and responsibilities helps to ensure transparency in the medicine registration process and the accountability of its committee members.

**Description:** The document should:

– be up-to-date; and

– be publicly accessible;

– list committee members by name and their expertise;

– include the roles and responsibilities of its members; and

– their accountability and financial benefits if any.

**Interpretation guidelines:** If there is no evidence of such a written document then the indicator will be rated with a 0. If the written document exists, rate the indicator as a *method 2* question.

Indicator I.10:

*Aren there written guidelines on conflicts of interest (COI) with regard to registration activities?*

**Rationale:** Given the potential for conflict of interest that could influence decision-making in the registration process, members of the committee or public officials involved in medicine registration processes, should be aware of what a conflict of interest implies and how it can affect their decision-making process. This would be stated in a COI policy or guideline. They should be obliged to declare officially any potential conflict of interest that could arise in their professional responsibilities.
**Description:** This question helps to check what systems are in place to identify and manage real or perceived conflict of interest issues. Written guidelines on COI should exist, as well as a standardized "declaration of conflict of interest" form. The guidelines should include as a minimum the following:

– definition of what a COI is;
– rules on accepting gifts;
– rules on reporting COI;
– mechanism protecting informers of COI;
– actions to be taken in case of failure to comply with guidelines;
– evidence of enforcement of these regulations (evidence that these forms are in fact systematically completed and reviewed by the members of the committee and public officials involved in the registration process).

**Interpretation guidelines:** If there is no evidence of COI guidelines then the indicator will be rated with a 0. If the guidelines exist, rate the indicator as a Method 2 question.

**Indicator I.11:**

*To what extent do you agree with the following statement: "The members of the registration committee are systematically and objectively selected based on the written criteria in force in your country"? (see question I.8)*

**Rationale and description:** Criteria to select the members of the committee may exist and be as comprehensive as those set out in question 8, but in reality they may not be used systematically or they may not be used at all. Asking for KIs perceptions will bring valuable insight on the transparency of the selection process for registration committee members, and on the application (or non-application) of existing rules and regulations in a country.
**Interpretation guidelines:** *Method 3.*

**Indicator I.12:**

*Are there clear and comprehensive guidelines for the committee decision-making process?*

**Rationale:** To help ensure transparency, fairness and consistency in the decision-making process in registration, the committee should be operating under clear and comprehensive guidelines. In general terms a product should be accepted because it demonstrates quality, efficacy and safety.

The committee should provide an official written report on the results of the medicine evaluation, whether the product is accepted or rejected. This procedure discourages inappropriate action on the part of the committee and allows suppliers and manufacturers to appeal decisions, if necessary. This guidance is crucial for helping to ensure good governance of the committee, and that its decisions are based on scientific and independent grounds.

**Description:** Generally such a committee makes recommendations and/or gives advice to a high level government official (e.g. Minster of Health, Head of MRA, etc.), who will then have the responsibility to take the final decision (she/he will be held accountable for the final decision).

However the committee should be given clear guidelines for its decision-making process to make their recommendations. These guidelines should:

– be available in writing;
– be publicly available;
– describe clearly the mandate of the committee;
– specify the number of meetings the committee should convene;
– specify the procedures for reaching decisions;
– describe the committee’s reporting structure;
– set clear time limits for the review process; and
– the decisions made at the meetings need to be made publicly available.

**Interpretation guidelines**: If there is no evidence of such guidelines then the indicator will be rated with a 0. If the guidelines exist, rate the indicator as a method 2 question.

**Indicator I.13:**

*Is there an independent and formal appeals system for applicants who have their medicine applications rejected?*

**Rationale**: A formal appeals procedure in the registration process can promote transparency by creating a publicly available trail of documentation of how decisions are made by governments.

**Description**: A formal appeals process or a protest mechanism should be available to manage concerns and complaints from companies and others. Following communication of decisions made after review of an application for registration, firms should be able to file protests based on their view that they were unfairly evaluated and provide reasons and/or supplementary documents, which support the request for a second evaluation.

**Interpretation guidelines**: If a formal protest mechanism is in operation, then this indicator should receive a rating of 1. If there is no appeals mechanism to speak of, the rating should be 0.

**Indicator I.14:**

*To what extent do you agree with the following statement: “Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on their final decisions”?*
**Rationale:** Despite clear regulation or guidance on the application process, the selection of the registration committee members, and their decision-making process, gifts or other benefits may be offered to public officials or committee members. This information is usually known by those involved in the system, including your KIs. *It is a sensitive question to ask,* and the KIs may feel uncomfortable and hesitate to give a spontaneous answer. Before asking this question it may be useful to remind and reassure them of the confidentiality of their answers.

**Interpretation guidelines:** *Method 3.*

**Indicator I.15**

*To what extent do you agree with the following statement: "The registration committee meets on regular basis and keeps minutes for its meetings"?*

**Rationale:** Despite clear guidance on holding meetings, the registration committee may not meet on a regular basis or will not keep always the minutes. This information is usually known by those involved in the system, including your KIs. *It is a sensitive question to ask,* and the KIs may feel uncomfortable and hesitate to give a spontaneous answer. Before asking this question it may be useful to remind and reassure them of the confidentiality of their answers.

**Interpretation guidelines:** *Method 3.*

**Indicator I.16:**

*In your opinion, what types of unethical behaviour are common in the registration system in your country?*

**Rationale:** This indicator captures perceived types of corruption or unethical behaviour that undermine a well-functioning system. Registration office staff and committee members have the responsibility to ensure that the registration process is
completed in accordance with national regulations and procedures. It is therefore important that they carry out their activities professionally and with integrity and honesty. They should not place themselves under any financial or other obligation to outside individuals or organizations, or take gifts that might influence them in the performance of their official duties. Their decisions should be based solely on their objective evaluation findings.

**Interpretation guidelines:** *Method 4.*

**Indicator I.17:**

*If you were in a position of highest authority, what would be the first action that you would take to improve the registration process in your country?*

**Interpretation guidelines:** *Method 4.*
Annex 4

Registration essentials

(Copied from WHO transparency measuring instrument)

\textit{a) Legal basis}

There should be provisions within the medicine legislation:

- requiring the registration of medicinal products;
- defining the types of medicinal products that should be registered and those that should be exempted;
- requiring the definition of the criteria for registration of products;
- requiring renewal of applications for marketing authorization;
- listing requirements for handling variations;
- dealing with exemptions to marketing authorization;
- setting time limits for processing applications;
- setting the fees for registration;
- identifying the information that must be publicly released;
- defining the appeals system.

\textit{b) Written guidelines and procedures}

There should be written guidelines and procedures for registration. Such guidelines and procedures will help staff in the registration unit to understand their role in the process. It will also enable applicants to understand the process and the requirements to be met. The Medicine Regulatory Authority (MRA) should develop and disseminate the following to stakeholders:

- standard application form for submission of applications;
- guidelines on data and information to be submitted in support of an application for marketing authorization (format and content);
– written criteria for approving a medicinal product for marketing (registration);
– guidance on exemptions and fast track registration;
– terms of reference and operating procedures for external experts;
– guidelines for assessors on how to assess applications;
– guidance giving instructions, in which situations inspections (all kinds) are organized to verify the data;
– procedures for data archiving, data confidentiality and release for the public;
– procedures requiring active monitoring of adverse medicine reactions and reporting findings to the MRA;
– standard format for an assessment report;
– guidelines on timeframes for processing applications;
– written criteria for selecting external experts;
– guidelines on meeting with applicants;
– guidance on content of product information leaflets;
– guidelines on conditions attached to issued marketing authorization e.g. validity, post-licence trials, prescription-only medicines, pharmacy-only medicines, etc.;
– guidelines on conflict of interest;
– code of conduct for external experts and internal staff;
– procedures for an independent appeals systems;
– certificate of registration/marketing authorization.

All guidelines, procedures and guidance materials should be printed, published and made easily accessible to all interested parties. Where possible they should be posted on the MRA web site.

\textit{c) Qualified and experienced persons}
Decisions concerning quality, safety, efficacy and product information should be made by persons with suitable knowledge, training and practical experience of the subject. The MRA should have an adequate number of staff with diverse qualifications, such as pharmacy, chemistry, clinical pharmacology, medicine, law. Where such staff is not available internally, the MRA should use external experts with the necessary qualification, technical skills and work experience. Both external and internal persons should sign a conflict of interest declaration form and should be fully briefed on written codes of conduct.

**d) Premises and facilities**

Data submitted by applicants need to be stored with sufficient security. There should be adequate office space for staff to store dossiers and related documentation. There should be secured access to computers, Internet, Intranet and other communications systems.

**The process of assessment for marketing authorization**

The process of assessing applications involves the following steps:

– submission of application dossiers by applicant;

– checking the submission for completeness by the responsible person within the registration unit;

– entering application into the registry book and issuing the receipt;

– pre-licensing inspection of manufacturing site;

– testing of samples and validation of test methods;

– submission of inspection report and quality control report;

– review of dossiers, inspection report and analytical report by committee of assessors;

– approval/rejection of product for registration by assessors;
- giving decision in writing with reason to applicant;
- posting/publishing registered product on the national Gazette or web site together with essential information and making them accessible to all interested parties and the public;
- appeal by applicant in case of rejection;
- decision of appeals body to applicant and the Medicine Regulatory Authority;
- exceptions (fast track, other medicines, etc.);
- data archiving and making selected non-confidential information available to the public, etc.

**Decision-making process**

To help ensure transparency, fairness and consistency in the registration process the assessment of applications should be done by a committee of experts with the necessary scientific, medical and technical knowledge and skills. The committee should operate in accordance with written guidelines. A product should be approved only if it meets the criteria for registration as stated in the guidelines as well as in the legislation and regulations.

Assessors should provide an official written report on the results of their assessment and should indicate whether a product is accepted for registration or rejected. The decision making body (the Registration Department or the MRA) should make decision based on the report of the committee. The presence of written guidelines will discourage inappropriate action on the part of the assessors and allow suppliers and manufacturers to appeal against decisions that appear to be contrary to what the process should have yielded has the procedures been followed. Such guidelines are also crucial to ensure good governance in the assessment process and that decisions by the assessors are based on scientific facts and independent grounds. Having such
guidelines publicly available helps to ensure that everyone knows about the process and what the criteria are. Figure 2 shows the process of medicine registration commonly applied in countries.

**Appeals system**

The MRA should establish an independent appeal system mechanism for clients to lodge complaints if they are not satisfied with the decision of the authority. The appeal system could be administrative as well as judicial.
## Annex 5

### Scoring sheet

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Total: #DIV/0

***Final score: #DIV/0!

0.504

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The outline of the sheet is taken from WHO transparency measuring instrument and filled by the researcher.

** The average for each question is calculated only on valid responses and all D.K. and N.A. answers are discarded.

*** Score = total average/number of indicators x 10