

Measuring Transparency in Medicines Registration, Selection and Procurement

Four Country Assessment Studies



Australian Government
AusAID



World Health
Organization

**Measuring transparency in
medicines registration, selection
and procurement**

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Executive summary

Despite revolutionary scientific progress and the sustained efforts of the development community, access to good quality essential medicines remains very limited in many parts of the world. This health crisis has many complex causes, including poverty, under-investment in health systems and war. Corruption is another cause currently gaining increasing attention, as growing numbers of public health officials in ministries of health and national medicines regulatory authorities are recognizing the need for their institutions and personnel to work in a transparent and accountable environment.

The pharmaceutical sector is particularly vulnerable to corruption, which manifests itself in various forms, including bribery, fraud, favouritism, collusion and embezzlement at different levels of the medicines chain. The impact on people's health should not be underestimated, as children and adults may end up taking unsafe or low-quality medicines. In addition waste of public or private resources can have an enormous impact on the economy at national, hospital and household levels. Corruption also reduces the credibility of public institutions and the health profession, and erodes public trust.

Recognizing this long-standing problem, in 2004 WHO initiated the *Good Governance for Medicines Project*, which offers a technical support package for tackling unethical issues in the public pharmaceutical sector. Initially the countries implementing this project conduct an assessment measuring the transparency of national medicines regulatory agencies and public procurement systems. This is followed by a process of policy reform, promoting good governance and the application of ethical principles.

This report summarizes the findings of the transparency assessments carried out in the first four countries participating in the project, Lao People's Democratic Republic, Malaysia, the Philippines and Thailand. It provides a comprehensive picture of the level of transparency and potential vulnerability to corruption in three essential functions of the public pharmaceutical sector - registration, selection and procurement of medicines. The methodology provides both qualitative and quantitative information. In each country two national investigators collected data, conducting a series of interviews with carefully selected key informants.

General findings

Qualitative information revealed that although the four countries have different public sector procurement and medicines regulation profiles, they have some common strengths and weaknesses. For example, all countries have transparent (written and publicly available) procurement Standard Operating Procedures, but none required a conflict of interest form to be completed for members of the registration or selection committees.

The information collected and then converted using a rough quantification method into a zero to 10 scale, provides a score for each country and each function in terms of vulnerability to corruption (minimally to extremely). The scoring shows the vulnerabilities in the policy, regulatory and administrative structures and procedures at the time of the survey, but in no way implies the level of possible existing corruption in the countries reviewed.

Registration

All four countries were reported to have a list of registered pharmaceutical products, written procedures and a standard application form for submission of applications, and a committee responsible for registration of pharmaceutical products. However, at the time of the assessment none of the countries had a written document describing the composition and the terms of reference of the registration committee, nor a conflict of interest form for committee members.

The decision-making process appeared to vary greatly between countries, but each provides an official written document for all decisions regarding applications. An appeals process for those who have their applications rejected exists in most countries, but the level at which it functions varies.

Selection

All countries were reported to have a national essential medicines list, and publicly available criteria and transparent procedures for the selection process for inclusion in or deletion from the list. As with registration committee members, the members of the selection committee were not required to fill in a conflict of interest form.

In general, the criteria for choosing members of the selection committee scored quite low in all countries, but with a degree of variation. Terms of reference for the selection committee existed in some but not all countries, and they were not always publicly available. The decision-making processes were also found to have different levels of clarity and transparency.

Procurement

All four countries are reported to use competitive and transparent procedures to procure pharmaceutical products, with some variation in their practices. They also used an objective quantification method to determine the quantity of products to be purchased. The post-tender system to monitor and report suppliers' performance scored generally high in all four countries. However, the appeals process for applicants who have their bids rejected will need to be either instigated or strengthened, depending on the country. The indicator related to the audits of procurement offices scored low in most countries, showing the need to strengthen this service.

The existence and use of criteria for tender committee membership varied greatly between countries. In some countries membership is based on function, in others by field of expertise. Similarly, the management information system used to report product problems is different, manually documented in some countries and computerized in others, at central level in some countries and decentralized in others.

Conclusions and recommendations

Experience in promoting good governance shows that two basic strategies are needed, a "discipline approach" based on the legislative and administrative reforms necessary to establish transparent systems, and a "values approach", building institutional integrity through the promotion of moral values and ethical principles. The first strategy is by nature top-down, whereas the latter tends to be a bottom-up approach.

The results of the transparency assessments will provide the evidence for countries to revise and adjust their laws and policies as well as the administrative structures and processes in place to ensure transparency in medicines regulation and public procurement. The assessments will also provide a platform for discussion at national level on developing a national ethical framework and for implementing a strategy promoting good governance in medicines regulation and procurement. The strategy needs to include the development of codes of conduct, socializing the national ethical framework through a systematic process of reflection and training of government officials and health professionals. A whistle-blowing protection mechanism should also be established and a working group for coordinating and managing strategy implementation should be nominated.

1. Introduction

The 20th century witnessed revolutionary scientific advances in the development of new treatments and in improving human health. Yet at the beginning of the 21st century the most essential medicines remained unavailable, unaffordable, unsafe or improperly used in many parts of the world, despite intensive efforts by countries, development agencies and the donor community. This health crisis has many complex causes, including poverty, under-investment in health systems and war. Corruption is another cause currently gaining increasing attention, as growing numbers of public health officials within ministries of health and national medicines regulatory authorities are recognizing the need for their institutions and personnel to work in a transparent and accountable environment.

The World Bank identifies corruption as the single greatest obstacle to economic and social development. Corruption is often rampant at national level, and this includes the health and pharmaceutical sectors. For example, it is estimated that fraud and abuse in the health sector cost US\$ 12 to 23 billion annually in the USA, that in Cambodia, 5% of the health budget is lost in corruption and that in Uganda, two-thirds of medicines supplies are lost through corruption and fraud in hospitals.¹

The pharmaceutical sector is highly vulnerable to corruption and unethical practices, due in part to the high market value of pharmaceutical products. Moreover, the stakeholders involved are numerous, diverse and have different objectives. They include researchers, manufacturers, wholesalers, retailers, prescribers, sales representatives, regulators and policy-makers. Corruption can manifest itself in many forms and throughout the medicines chain. For example, in the form of bribery of a public official to facilitate the registration process of a medicine, favouritism when recruiting new staff or when selecting committee members, fraud or collusion in procurement, or thefts and embezzlement in the distribution chain.²

The impact of corruption in the pharmaceutical sector should not be underestimated. Although it is very difficult to measure, experience has shown that corruption in the sector has a three-fold impact:

1. A health impact – waste of public resources by purchasing expensive or non-essential products reduces government capacity to provide access to good-quality essential medicines. Equally, when purchasing agencies collude with suppliers and purchase poor quality products not only is public money wasted but also the health of consumers is adversely affected. Patients treated with poor quality medicines are not cured quickly - they suffer for longer and in some cases they may even develop resistance to treatment.

¹ Global corruption report. New York: Transparency International; 2006.

² WHO medicines strategy - countries at the core: 2004-2007. Geneva: World Health Organization; 2004. (WHO/EDM/2004.5).

2. An economic impact — when the budget of the public sector procurement agencies is wasted in purchasing expensive products instead of good-quality versions of the same products at cheaper prices, or when funds are mismanaged, it means wasting national foreign exchange reserves as well as national currency. Such practices impact very negatively on national health budgets and contribute to shortages of medicines.
3. A government image and trust impact — inefficiency and lack of transparency reduce the credibility of public institutions, and erode public and donor confidence in government capacity to deliver on promises.

Recognizing that corruption is a long-standing and immense problem, in late 2004 WHO initiated the *Good Governance for Medicines Project*.

It offers a means of tackling some of these issues as they appear within the pharmaceutical sector. The project has two main objectives:

- to raise awareness of the potential for corruption in medicines procurement systems and national medicines regulatory systems; and
- to minimize such corruption by promoting and implementing good governance within the public pharmaceutical sector.

The project is implemented through a three-step process:

- a) national assessment of transparency and vulnerability to corruption of national public procurement systems and of national medicines regulatory authorities;
- b) development and implementation, via a consultative process, of national ethical frameworks promoting good governance in the public pharmaceutical sector;
- c) socializing the national ethical framework by training national officials on good governance principles in the public pharmaceutical sector.

This report summarizes the findings of assessments carried out in the first countries participating in the *Good Governance for Medicines Project* - Lao People's Democratic Republic, Malaysia, the Philippines and Thailand - in the first six months of 2005. The findings were reported and discussed during the first annual "Bi-Regional Workshop on Promoting Ethical Practices in Medicines Registration and Procurement" held in Penang, Malaysia, 31 May - 2 June 2005. In 2006, Bolivia, Cambodia, Mongolia and Papua New Guinea joined the project by conducting national transparency assessments, and their findings will be the subject of another report.

2. Objective of the country transparency assessments

The objective is to provide countries with a comprehensive picture of the *level of transparency* and potential *vulnerability to corruption* of three pharmaceutical sector functions:

1. registration of medicines
2. selection of essential medicines
3. procurement of medicines.

This is an essential step prior to developing a national ethical framework promoting good governance in the public pharmaceutical sector and to revising related administrative procedures through a national consultation process.

The project's vision is that the transparency assessment is not an end in itself, but is rather the beginning of a process aimed at bringing long-lasting changes in the efforts to promote good governance practices among health professionals in the public pharmaceutical sector. The assessment is an essential first step as it provides the evidence and the framework for building a pharmaceutical sector that is more transparent and accountable in participating countries, which in turn will help to improve equitable access to good-quality, safe medicines.

3. Methodology

The methodology used in this assessment provides both qualitative and quantitative information on the level of transparency present in three functions of the public pharmaceutical sector - namely registration of pharmaceutical products, selection of essential medicines and procurement. It collects qualitative information on structural indicators and a rough quantification is then used to define the level of transparency for each function.

3.1 Data collection method

The assessment instrument contains three questionnaires, one for each function (see annexes 1-3).¹ Each questionnaire is used with key informants (KIs) selected according to explicitly defined criteria. At least 10 KIs are interviewed for each function to provide a minimum amount of information, and the data provided are compared and confirmed where possible. In this way, a minimum of 30 KIs are interviewed in each country.

KIs are selected because of their first-hand knowledge and/or involvement in the pharmaceutical sector. For each function, they should include both senior and junior professionals, and represent the public and private sectors, including civil society organizations.

3.2 Data analysis and scoring

In order to minimize subjective interpretation of KIs' responses, each indicator is formulated to require a binary answer (yes/no). Further, interviewers must request documents from key informants in order to validate positive responses. In this methodology, a "yes" is given a value of one (1) and a "no" is given a value of zero (0). A value of one represents low vulnerability to corruption (as long as it is supported by the existence of a publicly-available document that describes the process or decision criteria). A rating of zero represents potential vulnerability to corruption since the absence of a standardized process or decision criteria provides decision-makers with broad discretion in their decision-making.

¹ The draft assessment instrument used in the Good Governance project is being tested and further refined in the light of the experience gained in countries. The version used in these four initial countries is dated 8 December 2004. The subsequent version, used in the three additional countries which have recently joined the project, includes two additional functions, control of medicine promotion and inspection of establishments. In the future, other functions (e.g. clinical trials, distribution) may also be included, based on availability of resources.

Once all the interviews with KIs are complete and all indicators are rated according to the criteria, an average rating is calculated for the questions concerning each function (registration, selection and procurement). Using a quantification method the results are converted to a zero to ten (0.0 to 10.0) scale, and are interpreted as representing the following degrees of vulnerability to corruption.¹

0.0 -2.0	2.1 -4.1	4.1-6.0	6.1-8.0	8.1 – 10.0
Extremely vulnerable	Very vulnerable	Moderately vulnerable	Marginally vulnerable	Minimally vulnerable

3.3 National investigators

Two national investigators (NIs) were selected for each country to undertake the assessment. To ensure an objective interpretation of the results, NIs are chosen from independent groups outside the Ministry of Health. Given that the subject under review may raise sensitivities in some countries, it is essential for the credibility of the results that the assessments are conducted by senior professionals from well-recognized and trusted organizations in the country. This was the case in this first round of national assessments, as they included a dean, professors and senior lecturers and independent consultants. Five NIs were from academia (pharmacy, public health), one from a research institute, one from a nongovernmental organization and one from an independent consulting firm. Before conducting the assessments in their respective countries, the eight NIs attended a preparatory meeting on 25-26 November 2004, in Manila, the Philippines, during which they were introduced to the WHO methodology.

¹ For more details and exact quantification method used, see assessment instrument.

4. Findings and discussions

The overall scores for each country and each function are summarized in Table 1.

Table 1: Vulnerability scale scores in registration, selection and procurement for all countries

	Lao PDR	Malaysia	Philippines	Thailand
Registration	5.6	6.8	6.8	7.0
	Moderate	Marginal	Marginal	Marginal
Selection	6.1	5.7	6.1	8.0
	Marginal	Moderate	Marginal	Marginal
Procurement	6.9	7.1	8.5	7.1
	Marginal	Marginal	Minimal	Marginal

4.1 General

Even though the four countries under review have different public sector procurement and medicine regulation profiles, the findings show some common strengths and weaknesses. For example, among the common strengths are having an information system for the registration process of pharmaceutical products, including a defined minimum level of information, having an official national list of essential medicines and transparent procurement Standard Operating Procedures (SOP). One common weakness in all four systems is the lack of a conflict of interest (COI) form or guidance for the members of committees responsible for the registration of pharmaceutical products or for the selection of essential medicines.¹

It is important to note that this scoring indicates vulnerability to corruption, given the policy/regulatory and administrative procedures in place at the time of the survey. It does not imply in any way that one country's system is more corrupt than another. At the time of writing, many countries have already taken steps to develop national ethical frameworks and to revise some administrative procedures, so that a new assessment would result in higher scores. The scoring system is meant to help countries monitor progress in their efforts to improve transparency and good governance practices in the public pharmaceutical sector over time.

¹ Thailand has a COI form for the committee responsible for the selection of essential medicines, however it does not include some basic information examined in this assessment, and so scores low.

4.2 Registration

In all four countries, registration of pharmaceutical products is the responsibility of a regulatory agency, which is under the Ministry of Health. The names given to these regulatory agencies differ between countries, as summarized in Table 2 below. These names and acronyms will be used when referring to the findings of each country.

Table 2: National medicine regulatory authorities

Lao PDR	Ministry of Health (MoH)	Food and Drug Department (FDD)
Malaysia	Ministry of Health (MoH)	National Pharmaceutical Control Bureau (NPCB)
Philippines	Department of Health (DoH)	Bureau of Food and Drug Registration (BFAD)
Thailand	Ministry of Public Health (MoPH)	Thai Food and Drug Administration (Thai FDA)

4.2.1 Strengths

The common **strengths** found in the four countries include the existence of:

- A list of all registered pharmaceutical products and an information system for the registration process of pharmaceutical products which include a defined minimum level of information, such as the product description, the name of the manufacturing company, the date of the registration, and the name and contact information of the company registering the medicines (indicator 1).
- Written procedures on how to submit and assess applications for registration of medicines products. These are publicly accessible in all four countries, and describe the process to follow and the fees required (indicators 2 and 16).
- A standard application form for submission of applications, which is publicly accessible and readily available at a government office or on a web site (indicators 3 and 4). All countries reported that their forms require a minimum level of information, such as the name of the product (including the generic name), a summary of product characteristics (pharmacological action, therapeutic classification) and the packaging material.
- A formally established and operational committee responsible for registration of pharmaceutical products composed of professionals with technical skills, which meets on a regular basis (indicator 5). A summary description is included in Table 3.
- The existence of a mechanism whereby once decisions are made, the responsible committees provide official written documents for all decisions regarding applications, explaining the reasons for rejection if necessary. (indicator 8).

Table 3: Summary description of committees responsible for registration of pharmaceutical products

Country	Description of committee	Other comments
Lao PDR	Established by MoH decree in 1998 composed of the FDD director (chief of committee), heads of other departments (Curative Department, Food and Drug Quality Control Centre, staff of the Drug Unit), and specialists scheduled to meet every 3 months.	If medicines already included on the EML, the head and staff of the Drug Unit can make the decision and then write a report to the chief of the committee.
Malaysia	Drug Control Authority (DCA) set up by law (Control of Drug and Cosmetic Regulation - CDCR) in 1984 members are specified in the law and appointed by the Minister of Health includes mostly pharmacists and doctors meets once a month.	
Philippines	Products and Services Division (PSD) is the office in charge three types of committee identified for making decisions on applications evaluation committee, within the PSD advisory committee composed of external consultants expert in their field management committee.	The management committee was known to meet regularly, but KIs gave contradictory information on the regularity of evaluation committee meetings.
Thailand	Drug committee set up by Drug Act appointed by the Minister of Health every two years 19-23 members by law 14 regular members, of which 9 by position (usually head of organization) and 5 are ex-officio members (appointment based on their positions in pharmaceutical-related organizations) 5-7 members are appointed from pharmaceutical and medical experts the committee appoints sub-committees to assist them in their tasks.	Sub-committees are in practical terms responsible for decisions to approve or reject applications. They submit their decisions directly to the Secretary-General of the Thai FDA for signature, without going through the drug committee, if these are straightforward. However, problematic applications are considered by the committee.

4.2.2 Weaknesses

The common areas identified as **requiring strengthening** in the four countries include the need to:

- Develop a written document that describes clearly the *committee's composition and terms of reference*. A basic document describing the composition of the committee usually existed, however the assessments demonstrated that there was a lack of information on the terms of reference and that these documents were incomplete. For example, they were not up-to-date, did not describe the duties and responsibilities of committee members or were not always easily accessible (indicators 6 and 9).

- Develop a *conflict of interest form* that members of the committee and public officials are obliged to complete. A conflict of interest (COI) form needs to define what a COI is and the sanctions to be applied in case these are not declared (indicator 11). Here all countries scored zero.

4.2.3 Variations

- The *decision-making process of the responsible registration committees*, including their role and the way they reach decisions, is different in the four countries (indicators 7, 10 and 15). It is important to reiterate that in all four, regardless of the decision-making process, all decisions are supported with an official written document (indicator 8).
- In the Lao People's Democratic Republic, the committee reaches its decisions by majority, and these then need to be signed off by the head of the medicines regulation authority (Director, FDD).
- In Malaysia, the DCA itself can make the decisions on whether to approve or reject an application through consensus or voting, without having to refer to another entity. However there was a perception among some KIs that the decision-making process is not democratic enough. The Malaysian NIs' interpretation is "This may not truly indicate vulnerability to corruption, as perception may play a dominating role here, or is due to the fact that sometimes civil servants are not known to be very vocal when having to attend a meeting chaired by a very senior officer".
- In Thailand, the responsible sub-committees act in an advisory capacity and report to the Secretary General of the Thai FDA who makes the final decision. However, it was reported that usually all of the sub-committees' proposals are passed.
- In the Philippines, the PSD evaluation committee does not make or implement final decisions but submits the recommendations to higher authorities for action. Based on the information received from KIs, the decision-making role of the committee scored rather low. See Box 1 for details of the decision-making process.

Box 1: Philippines' registration decision-making process

- | |
|---|
| <ul style="list-style-type: none">➤ applications first evaluated by junior and senior evaluators from PSD➤ then sent to respective members of the advisory committee, according to their expertise➤ finally, evaluation results sent to the head of PSD who sends the recommendation to the BFAD Director➤ BFAD Director may make the decision or refer special cases to the management committee. |
|---|

An *appeals process for applicants who have their application rejected* exists in Malaysia, the Philippines and in Thailand, although it functions at different levels but no such process exists in the Lao People's Democratic Republic (indicator 12). The law in Malaysia and the Philippines prescribes that an applicant can present an appeal directly to the highest authorities after the issuance of the committee's decision. This fact is well known in both the private and public sectors in the Philippines, however in Malaysia some KIs were unaware of it. In Thailand, detailed procedures are not clearly defined and all appeals are submitted to the same committee that made the original decision on the application.

4.3 Selection

The names and the formats of national essential medicines lists (EMLs) differ in the four countries. It can exist as a simple list including the name and the therapeutic category, or it is incorporated in a more comprehensive document with more detailed information (indications, side-effects, etc.), often the national formulary. In some countries both versions exist, but usually one is used more than the other. The terminologies and common format used in each country to refer to their national EML are summarized in Table 4 and will be used in this report.

Table 4: Terminology used by countries to refer to their national essential medicines list

Lao PDR	National Essential Drugs List (NEDL)
Malaysia	Blue Book or MoH Drug Formulary
Philippines	Philippine National Drug Formulary (PNDF)
Thailand	National List of Essential Medicines (NLEM)

4.3.1 Strengths

The common **strengths** found in the four countries under review include:

- The availability of a *national essential medicines list*, which received the maximum score of 1 in all four countries (indicator 19). This means that not only did the national EML exist, but also that KIs knew about it. The following points were noteworthy:
 - The responsibility for developing the national EML lies with the national drug regulatory authority in the Lao People's Democratic Republic and Thailand, whereas in Malaysia and the Philippines it falls within the mandate of the MoH and DoH respectively.
 - In Malaysia, the list is reported to be available on the Government web site.
 - In Thailand, the EML is prepared and approved by the *Sub-committee on Development of the Essential Drugs List*, which operates through 15 working groups divided by speciality (e.g. antimicrobial, urology, cancer, etc.). The list is available on the Thai FDA and MoPH web sites, and hard copies are distributed nationwide.

- The *criteria for the selection process* for including or deleting medicines from the national EML were found to be publicly available and clearly written (indicators 21 and 22). The criteria for inclusion of new products on the EML included priority health needs and cost-effectiveness.
- The *procedures for the selection process* were also found to be transparent and in line with recommended WHO procedures (indicators 20 and 25), such as medicines being listed by their generic name or linked to national standard treatment guidelines.

4.3.2 Weaknesses

The common areas identified as **requiring strengthening** in the four countries under review include the need to:

- Develop a *conflict of interest form* that members of the selection committee are obliged to complete. A conflict of interest (COI) form needs to define what a COI is and define the sanctions to be applied in case these are not declared (indicator 30). It should be noted that Thailand is the only country that reported having a conflict of interest form, however at the time of the assessment the form did not define what sanctions will be applied in case of breaches and so this indicator scores poorly.
- All countries reported not having a specific *law or regulation prohibiting committee members to accept gifts* from pharmaceutical companies (indicator 29). In Malaysia and the Philippines the government public servants guidelines, which clearly prohibit such acts, are considered to contain the general principles to follow.

4.3.3 Variations

- The *criteria for selecting members* of the selection committee (indicators 23 and 27) on average scored rather low for all four countries, with some degree of variation:
 - In the Lao People's Democratic Republic, committee members included experts from different fields, and membership was on a rotating basis, but the criteria for selecting the members were not defined
 - In Malaysia, although members of the committee are selected based on their expertise and position, the criteria are not publicly available, their appointment is not made public and there was no indication that membership is rotating
 - In Thailand, the criteria for selecting members exist and most KIs knew that they are publicly available. Rotation of membership is not required, although in practice rotation is commonly applied.
 - In the Philippines, the terms of membership are in the public domain, however half of the KIs were unclear as to whether these are publicly available or not. Rotation of members is done at national level.

- *Terms of reference for the selection committee*, describing its role and responsibilities exist in the Philippines and Thailand, and are publicly available. They exist in Malaysia but are not publicly available. In the Lao People's Democratic Republic the role and purpose of the committee are not clearly defined (indicator 26).

Table 5: Detailed information on selection committees' terms of reference
(indicator 26)

Sub-criteria	Lao PDR	Malaysia	Philippines	Thailand
Terms of reference exist	no	yes	yes	yes
Terms publicly available	no	no	yes	yes

- The *decision-making process included in the SOPs* have different levels of clarity and transparency (indicators 24 and 28).
 - Thailand scores very high for both indicators. The decisions made by the selection committee are as a rule widely disseminated and available on the Internet.
 - In Malaysia, the decision-making process is regarded as democratic by KIs, the decisions are disseminated to public facilities and included in the "Blue Book", however the dissemination is not made public or put on the web site.
 - In the Philippines, the committee uses clear rules for decision-making and decisions are reached by majority, but as in Malaysia it appears that once made, decisions are only communicated to a limited number of key players and are not disseminated widely.
 - In the Lao People's Democratic Republic, decisions are reached through majority vote, but no information on the level of dissemination was reported.

Table 6: Selection committees' decision-making process (indicators 24 and 28)

Selected sub-criteria	Lao PDR	Malaysia	Philippines	Thailand
Decisions publicly available	yes	yes	yes	yes
Decisions widely disseminated	---	no	no	yes
Decisions in democratic manner	yes	yes	yes	yes

4.4 Procurement

4.4.1 Strengths

The common **strengths** found in the four countries include:

- *Procedures for the procurement of pharmaceutical products are competitive* (indicator 33), with some variations in the practice between countries as summarized in Table 7 below.

Table 7: Summary of information on procurement law/regulation and practices

Country	Requirements by law/regulation	Common practice
Lao PDR	Ministry of Finance decree N°0063/MoF and MoH Cabinet Notice N°052/MoH authorizes four methods: <ul style="list-style-type: none"> - public bidding when value of 150 to 1,500 million kip - limited bidding when value of 30 to 150 million kip - price comparison when less than 30 million kip - direct contracting when emergency or less than 1 million kip. 	<ul style="list-style-type: none"> - Most of the time price comparison is being used because of the limited Government budget.
Malaysia	<ul style="list-style-type: none"> - Competitive national tenders through centralized purchasing mechanism involving multiple sources of supply for <i>large volumes</i> - Direct purchase through quotations by individual hospitals for <i>selected or small volumes</i>. 	<ul style="list-style-type: none"> - Mainly through negotiated pricing, with a concession holder approved by the Government. - Competitive bidding to a certain extent for fair and efficient procurement. <p>KIs believed procedures are sufficiently competitive.</p>
Philippines	Government Procurement Reform Act R.A. 9184 requiring competitive bidding and the use of standardized bidding documents by all Government agencies.	<ul style="list-style-type: none"> - Bulk of medicines procurement in DoH conducted through public bidding. - In 2005, the budget for procurement of medicines was earmarked as follows: <ul style="list-style-type: none"> - Ph peso 1.9 million through public bidding - Ph peso 363,713 through alternative methods of procurement.
Thailand	Regulation includes 3 levels of purchasing: <ul style="list-style-type: none"> - Bidding or "electronic auction" when purchasing value is more than 2 million baht - Tender value between 100,000 baht and 2 million baht - Negotiation when value less than 100,000 baht. 	Purchasing by special means is possible if it is a cabinet decision. Special purchasing is also possible when it is impossible to purchase via the regulated methods, for example when there are no tender offers.

- The use of *transparent procedures for procurement of pharmaceutical products* (indicators 34, 35, 37, 40, 41, 50 and 53).¹ All four countries have written procedures that are publicly available and include specific requirements such as the use of generic names and procurement to be based on the NEML.

Table 8: Comparative analysis of transparency in procurement procedures

no	Indicator	Lao PDR	Malaysia	Philippines	Thailand
34	Clearly written and updated in last 5 years	Yes	Yes	Yes	Yes
35	Publicly available & disseminated	Yes	On web site	On web site	Yes
37	Based on NEML	Most of drugs	Yes, included in "Blue Book"	Most of drugs	Yes
40	Contract specifications publicly available and included in tender documents	Yes	Yes	Yes	Yes, for purchase value over 100,000 baht
41	Tenders publicized	Rarely publicized (only when value over 150m kip)	Yes, in local newspaper, international publications and/or MoH web site	Yes	Yes, for purchase value over 100,000 baht
50	Use of generic names	Yes	Yes	Majority of drugs	yes
53	Adjudication criteria publicly available and included in tender package	Yes	Yes	Yes	Mostly not

- The use of an *objective quantification method* to determine the quantity of pharmaceutical products to be purchased by government officials (indicator 36). The use of historical data based on previous consumption and basic national health care indicators were reported by all countries.
- A *clear procedure to ensure that payment is linked to drug delivery* is well established in all four countries (indicator 47). This procedure usually records among other things the dates of payment and the list of all purchase receipts.
- The *post tender system to monitor and report on suppliers' performance* generally scores high in all countries with some minor variations between countries. It is also generally believed that suppliers' performance is linked to future decisions (indicators 43 and 44).

¹ All 7 indicators are being analysed together to reflect the revised assessment instrument's structure in which they are all clustered as sub-questions in one indicator.

- In Malaysia, this is done at end-user level (hospitals and health centres) with a specific form available for this purpose.
- In Thailand, there is no official requirement and it is left to the discretion of hospitals to decide. However many of them evaluate suppliers performance, specially those ISO 9000-certified hospitals.
- In the Philippines, it was reported that the DOH maintains a "blacklist" of suppliers and the majority of KIs believed that the information it contains is used when considering future decisions. However a KI from an NGO reported that in one instance a company which had performed poorly was nevertheless subsequently awarded an important contract.

4.4.2 Weaknesses

The common area identified in the assessment **in need of strengthening** include the need to:

- Set up a *formal appeals process* for applicants who have their bids rejected (indicator 42) in which a representative from the company can file a protest based on the view that the tender excludes them unfairly or the tender process was flawed.
 - In Malaysia, bidders do not have the opportunity to place an appeal and the tender committee's decision is final. However it appears that early in the tender process, if the specifications of a particular product are found to be "leaning" towards a particular brand, at that stage competitors have the right to complain and request the MoH to call for a new tender with new specifications.
 - In the Philippines, a formal appeals mechanism does exist, but the assessment showed that no bidders have used it, as all issues were resolved during the bidding conference. Finding no evidence of its use, this indicator was rated 0.
- *Audits of procurement offices* are conducted in all countries but the related indicator scores low in all but the Philippines (indicator 52). This is mainly because the specific criteria under review in this assessment are not met.
 - In the Lao People's Democratic Republic, an annual audit is conducted by the Ministry of Finance (MoF), but there were contradictory opinions as to whether the results are published and whether they report the operating costs of the procurement unit, the quantities of products and the beneficiaries.
 - In Malaysia, this indicator also scores poorly as annual auditing is conducted by the Ministry's internal auditors and not by independent auditors. The audit report is presented to Parliament and is open to scrutiny by its members.
 - In Thailand, although there is an annual audit, this indicator has a low score as it does not cover all the criteria sought in the assessment.

- In the Philippines, however, the indicator receives a high score as the Commission on Audit (COA) conducts regular annual post-audits for all Government agencies, including the DoH. The CoA is the Philippines' Supreme Audit Institution, and its independence is declared in the Constitution. The annual audit report includes the criteria being sought by the assessment and is available on the CoA web site: <http://www.coa.gov.ph>.

4.4.3 Variations

- The existence and use of *specific criteria for tender committee membership* varies from country to country (indicators 38 and 39).
 - In the Lao People's Democratic Republic, there are no specific criteria, but regulations dictate the membership by function and members are nominated by the Ministry of Health. All members are reported to be high-level officials, such as the director of cabinet of the MoH, the director or deputy of the inspection department, the deputy director of the planning and budget department, etc. NIs reported that the membership changes every two years on average.
 - In Malaysia, the MoH has assigned specialists from various fields and pharmacists from public health facilities as members of the tender committee, but NIs found no indication of the length of service. It appeared that some members have been on the committee for a long time.
 - In the Philippines, based on the Procurement Act, the DoH has adopted clear guidelines for tender committee membership. Its chairman is a third ranking permanent official of the DoH, and the rest of its members are at least fifth ranking officials. Members serve a one-year term, which can be renewed at the discretion of the agency.
 - In Thailand, no written document was available at the time of the assessment, but KIs mentioned that selection was usually based on functions (e.g. director, pharmacist). It appears that membership changes mainly because of movement of staff around Thailand.
- The *management information system used to report product problems* in procurement is different from country to country (indicator 45).
 - In the Lao People's Democratic Republic, the management information system is a manual one and appears to contain all the criteria assessed.

- In Malaysia, the reporting of product problems and account-keeping are left to the purchasing hospitals and health centres. KIs reported that there seem to be no product records, no proper monitoring of suppliers and facility performance, and no quality assurance record. KIs appeared to be were aware of these shortcomings.
 - In the Philippines, it was reported that there is a computerized management information system tracking the various criteria covered in this assessment, but NIs found that the system is not fully on-line and records are kept manually. However, when interviewing the KIs, it appeared that a large majority were not aware of such a tracking system, leading to a poor score compared with other indicators.
 - In Thailand, the system is run by the Department of Medical Sciences for reporting quality issues, and all information is available on its web site at: <http://www.dmsc.moph.go.th>.
- *Lot quality testing*, as part of procurement procedures, is carried out at varying levels in the countries (indicator 46).
 - In the Lao People's Democratic Republic and the Philippines, pharmaceutical products purchased are physically inspected after delivery. In Laos, a special committee examines the shipment before making the payment. In the Philippines, the physical quality and quantity are checked. Not only are the terms of the contract checked, but the bio-efficacy of the medicines delivered are also tested.
 - Malaysia and Thailand both score poorly with this indicator, as KIs felt that lot quality testing is not standard practice.¹

¹ However in Thailand, the Department of Medical Sciences routinely samples the problematic drugs for quality testing. In addition, the hospitals draw samples for quality checking when they purchase from new suppliers and whenever suspicions arise during product inspection.

5. Conclusions and recommendations for action

General

If a country wishes to have medicines regulation and procurement systems that are minimally vulnerable to corrupt practices, certain transparent structural and process arrangements need to be in place. The assessment methodology presented here allows countries to take stock of how transparent their operating structures and processes are, the strengths each country can capitalize on, and the loopholes that may leave room for corrupt practices and which need to be addressed.

Experience in promoting good governance shows that efforts to address corruption require two basic strategies, a "discipline approach" and a "values approach". The discipline approach, based on legislative reforms, establishes the laws, administrative structures and processes needed to establish transparent medicines regulation and procurement systems. It also defines the legal sanctions to be applied for not complying with the law. A "discipline approach" is therefore by nature top-down. The values approach promotes institutional integrity through promotion of moral values and ethical principles and attempts to motivate ethical conduct by public servants. The values approach tends to be bottom-up. It is essential to keep in mind that neither strategy in itself is sufficient, and a coordinated application of both is required for significant impact.

The results of their assessment will help countries in applying the discipline approach described above. In the light of the findings, it is recommended that each country adjusts its laws, administrative structures and procedures in terms of medicines regulation and procurement. These changes will need to be discussed in the national workshop(s) when the studies end. To date, all four countries have held at least one national workshop.

The national workshops serve both as a platform to establish the values approach, and more concretely to initiate the process of developing a National Ethics Infrastructure that promotes good governance in medicines regulation and procurement. A National Ethics Infrastructure is a national policy document that establishes norms and values to guide the performance of roles within an organization. Such policy documents need to be developed in consultation with key stakeholders, such as ministry of health officials, the private pharmaceutical sector, the ministry of finance, civil society organizations (CSOs) and academia. After the consultation process, it will need to be officially adopted by the relevant public institution.

Specific

Promoting good governance in medicines regulation and procurement is still a new area of work for WHO. The specific recommendations below are based on experience gained by WHO while working with countries piloting the *Good Governance for Medicines in the Public Sector* project. They are also based on the lessons learnt by other organizations that have been most active in curbing corruption and promoting good governance during the last decade, such as the World Bank, Transparency International and the Organisation for Economic Co-operation and Development.

1. Hold a national workshop with key national stakeholders to:
 - a) share the results of the national transparency assessment and review the recommendations made by the national investigators
 - b) agree the main elements of a national ethical framework aimed at promoting good governance for medicines regulation and procurement.
2. Publish the national assessment report on transparency and vulnerability to corruption, and ask for comments from key partners.
3. Revise laws, administrative structures and procedures based on the findings of the assessment and discussions during the national workshop, to ensure transparent medicines registration, selection and procurement processes.
4. Develop a National Ethics Infrastructure for promoting good governance in medicines regulation and procurement through a consultation process based on consensus-building. This can be based on WHO's model Ethics Infrastructure for Good Governance in the Pharmaceutical Sector¹ and will need to be adapted to the specific needs and context of each country.
5. Officially adopt the National Ethics Infrastructure, giving political backing to government officials to take the actions necessary to promote good governance in the pharmaceutical sector.
6. Develop an ethical framework and codes of conduct based on moral values and ethical principles as measures to prevent unethical behaviour by public servants in performing their duties. The codes of conduct will set out the application of ethical principles in concrete terms.
7. Socialize the national ethical framework and the codes of conduct. Socialization of an ethical framework requires a process of systematic reflection and training — in this case, of government officials and health professionals. Such reflection and training are essential to generate civil servants' sense of ownership of and personal identification with an ethical framework. These in turn are vital to creating the motivation necessary for sustained application of an ethical framework.

¹ WHO Ethics Infrastructure for Good Governance in the Pharmaceutical Sector. (In preparation).I

8. Establish a whistle-blowing protection mechanism. Such a mechanism will need to protect the whistle-blower from victimization and retaliation from those involved in corrupt practices. At the same time it should protect public servants from irresponsible and unethical whistle-blowing that could damage their reputations and careers due to false allegations.
9. Nominate a working group that will be responsible for coordinating and managing implementation of the *Good Governance for Medicines in the Public Sector* project at national level. Additionally, the working group will evaluate the programme on a regular basis. It is suggested that the transparency assessment is undertaken every 2 years.

The implementation of the *Good Governance for Medicines in the Public Sector* project is a process. Changes will not happen overnight, but experience has shown that results in the short term are possible. Furthermore, there is no magic, standard formula that can be applied universally. Each country will need to devise a strategy according to its own needs and reality, and adjust this strategy over the years through a systematic process of planning, implementation and evaluation.

Annex 1 - Questionnaire registration

Date: _____
Name: _____
Position: _____

#	Indicator	Criteria	Rate
1	Does the drug registration process have an information system?	Criteria	
		Name of company registering the drug	
		Contact of company registering the drug	
		Name of manufacturing company	
		Country of product manufacturing	
		Date of registration	
		Product description	
	Total		
	Score*		
2	Are there written procedures on how to register a drug in the market for applicants and for assessors?	Criteria	
		Public access	
		Process description	
		Fees mentioned	
		Authorities involved in the registration process	
		Total	
		Score*	
3	Is there a standard application form?	Criteria	
		Product name	
		Product manufacturer	
		Generic names of active substances	
		Pharmacological action	
		Therapeutic classification	
		Packaging insert	
	Total		
	Score*		
4	Is this document publicly available and easy to access?	Criteria	
		Readily available at government office or website	
		Total	
	Score*		
5	Is there a formal committee responsible for drug registration? If yes, what criteria are used for selecting committee members?	Criteria	
		Formally established	
		Composed with professionals with technical skills	
		Meet on a regular basis	
		Total	
	Score*		
6	Is there an organigram that describes the composition of the committee available as a public document?	Criteria	
		Member names	
		Member responsibilities	
		Up to date	
		Public access	
		Total	
	Score*		

* Score = Total/Number of criteria for respective indicator

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#	Indicator	Criteria	Rate
7	<i>Is the committee responsible for decision-making or does it act in an advisory capacity</i>	Criteria	
		Evidence that committee decisions are implemented	
		Total	
		Score*	
8	<i>Does the committee provide an official written report for all decisions (e.g. accepted and rejected files)</i>	Criteria	
		Existence of rejection criteria for registration Document explains reasons for rejection	
		Total	
		Score*	
9	<i>Do terms of reference exist which describe the purpose of the committee, its processes, duration, etc.? And, if so, are these available publicly?</i>	Criteria	
		Existence of terms of reference Terms of reference publicly available Terms of reference comprehensive	
		Total	
		Score*	
10	<i>How does the committee reach its decision (for example, is a qualified majority required, consensus, etc.?) Are these procedures documented?</i>	Criteria	
		Documented procedures for decision-making	
		Total	
		Score*	
11	<i>Are members of the committee or any other officials involved in the medicine registration process formally required to declare any conflict of interest</i>	Criteria	
		Existence of standard form for declaring conflict of interest Standard form publicly available	
		Total	
		Score*	
12	<i>Is there an appeals process for applicants who have their drug applications rejected?</i>	Criteria	
		Formal appeal process in place which is transparent Evidence protest mechanism is used	
		Total	
		Score*	
13	<i>Have there been drug recalls in the past 3 years?</i>	Criteria	
		Example of a drug recall with clear explanations Evidence that information shared with professionals and consumers Evidence of clear procedures for drug recalls	
		Total	
		Score*	
14	<i>Are there formalized procedures to deal with reporting of drug safety and efficacy?</i>	Criteria	
		Information administration procedures Availability of information on side effects of medicines	
		Total	
		Score*	

* Score = Total/Number of criteria for respective indicator

#	Indicator	Criteria	Rate
15	<i>Who does the committee report to and is this person responsible for making the final decision?</i>	Criteria	
		Open and transparent procedures for decision-making	
		Democratic decision-making	
		Total	
		Score*	
16	<i>Is the registration fee set by law or regulation and publicly available?</i>	Criteria	
		Regulation or law includes registration fee	
		Fee information publicly accessible	
		Total	
		Score*	
17	<i>Is the time from application to decision-making uniform from application to application?</i>	Criteria	
		Consistency in registration time across sample of at least five	
		Total	
		Score*	
18	<i>Are there drugs in the market that are non-registered?</i>	Criteria	
		No evidence of non-registered drugs on the market	
		Total	
		Score*	
Total score for registration			

* Score = Total/Number of criteria for respective indicator

Annex 2 - Questionnaire selection

Date: _____
Name: _____
Position: _____

#	Indicator	Criteria	Rate
19	<i>Does the government have a national essential medicines list?</i>	Criteria	
		Evidence of a national essential medicines list	
		Total	
		Score*	
20	<i>Is the essential medicines list in line with WHO EML model?</i>	Criteria	
		Officially adopted, published and disseminated	
		By generic name	
		By level of health care	
		Linked to national standard treatment guidelines	
		Evidence that widely disseminated to health professionals	
		Total	
		Score*	
21	<i>Is there evidence of clear written criteria for including and eliminating drugs from the EML?</i>	Criteria	
		Rules/criteria for drug inclusion or elimination	
		Criteria available in written format in the public domain	
		Total	
		Score*	
22	<i>Is the inclusion of new products on the EML based on studies of cost-effectiveness and health needs?</i>	Criteria	
		Clear guidelines on the inclusion of new drugs based on cost effectiveness	
		Clear guidelines on the inclusion of new drugs based on health needs	
		Total	
		Score*	
23	<i>Is committee membership on the drug selection committee on a rotating basis or limited in time?</i>	Criteria	
		Limited or rotating membership	
		Terms of membership are in the public domain	
		Total	
		Score*	
24	<i>Are the decisions made by the selection committee publicly disseminated?</i>	Criteria	
		Decisions on selection process publicly available	
		Decisions widely disseminated	
		Total	
		Score*	
25	<i>Are generic medicines selected for the EML except in the cases when a generic substitute is not available?</i>	Criteria	
		Use of generic medicines primarily unless there is no generic substitute	
		Total	
		Score*	

* Score = Total/Number of criteria for respective indicator

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#	Indicator	Criteria	Rate
26	<i>Do terms of reference exist which describe the purpose of the selection committee, its processes, duration, etc.? And, if so, are these available publicly?</i>	Criteria	
		Existence of TOR for selection committee	
		TOR publicly available	
		Total	
		Score*	
27	<i>Are there clear criteria for committee membership?</i>	Criteria	
		Clear criteria for committee membership	
		Committee includes experts from different fields	
		Publicly available through government office or website	
		Total	
		Score*	
28	<i>Are there clear rules for decision-making for the committee decisions?</i>	Criteria	
		Decisions made by all members in a democratic manner	
		Clear rules for decision-making	
		Total	
		Score*	
29	<i>Is there a law or regulation prohibiting members of the drug selection committee from accepting support in kind or in cash from pharmaceutical companies?</i>	Criteria	
		Existence of laws or regulations	
		Total	
		Score*	
30	<i>Is there a "conflict of interest" form that members of the selection committee are obliged to complete? Are there clear sanctions for breach of these regulations?</i>	Criteria	
		Existence of declaration of conflict of interest form	
		Clear and comprehensible sanctions	
		Evidence of enforcements of these regulations	
		Total	
		Score*	
31	<i>Has any committee member worked in the past or is now working for the pharmaceutical industry?</i>	Criteria	
		No evidence of a member having connections to the pharmaceutical industry	
		Total	
		Score*	
32	<i>Is there an independent drug agency that provides unbiased information?</i>	Criteria	
		Independent drug information agency	
		Supplies information regularly	
		Total	
		Score*	
Total score for selection			

* Score = Total/Number of criteria for respective indicator

Annex 3 - Questionnaire procurement

#	Indicator	Criteria	Rate
33	<i>Are there competitive procedures for the procurement of pharmaceutical products?</i>	Criteria	
		Clearly established competitive procedures for procurement of drugs	
		Total	
		Score*	
34	<i>Does the government use written procedures (prepared within the previous 5 years) for drug procurement?</i>	Criteria	
		Clear written procedures	
		Up to date (revised in the last 5 years)	
		Total	
		Score*	
35	<i>Are these written procedures publicly available?</i>	Criteria	
		Accessible through government office or website	
		Dissemination of procedures to entities of interest	
		Total	
		Score*	
36	<i>Is there a clear algorithm, based on utilization of services and health needs to determine quantity and type of pharmaceuticals purchased?</i>	Criteria	
		Based on consumption historical data	
		Based on adjusted consumption	
		Based on morbidity	
		Based on service level projection	
		Total	
		Score*	
37	<i>Is drug procurement based on the national essential medicines list or hospital formularies?</i>	Criteria	
		Procured drugs are consistent with essential list and/or hospital formulary	
		Existence of documents demonstrating the above	
		Total	
		Score*	
38	<i>Are there specific criteria for tender committee membership?</i>	Criteria	
		Clear guidelines for committee membership	
		Membership criteria based on merit and effort	
		Total	
		Score*	
39	<i>Is the membership permanent?</i>	Criteria	
		Clear written procedures for tenure of membership	
		Changes on a regular basis	
		Total	
		Score*	

* Score = Total/Number of criteria for respective indicator

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#	Indicator	Criteria	Rate
40	<i>Are the contract specifications publicly available and distributed with the tender documents?</i>	Criteria	
		Clear written criteria for presenting a bid	
		Criteria are always included in all tender documents	
		Total	
		Score*	
41	<i>Are tenders for pharmaceuticals publicized in newspapers, gazettes, trade publications or other means?</i>	Criteria	
		Evidence of regularly publicized tenders	
		Total	
		Score*	
42	<i>Is there a formal appeal process?</i>	Criteria	
		Evidence of enforcement	
		Total	
		Score*	
43	<i>Is supplier performance monitored at least annually?</i>	Criteria	
		Records of monitoring of supplier performance	
		Records of monitoring of supplier's compliance with contract terms	
		Total	
		Score*	
44	<i>Is the information obtained from the monitoring used to influence future procurement decisions?</i>	Criteria	
		Government has list of past suppliers	
		Government has evaluation of supplier performance	
		Information used to influence future decision	
		Total	
		Score*	
45	<i>Is there a management information system used to report product problems in procurement?</i>	Criteria	
		System is clear and up to date	
		Contains product records	
		Contains monitoring of supplier and facility performance	
		Contains quality assurance records	
		Contains accounts receivable and payable	
		Total	
		Score*	
46	<i>Is lot quality tested as part of the procurement procedure?</i>	Criteria	
		Medicines shipments physically inspected	
		Systematic procedure to sample drug shipments	
		Total	
		Score*	
47	<i>Is there a clear procedure to ensure that payment is linked to drug delivery?</i>	Criteria	
		Records of each order placed and amounts due	
		Dates of payments	
		List of all purchase receipts	
		Total	
		Score*	

* Score = Total/Number of criteria for respective indicator

#	Indicator	Criteria	Rate
48	Are unit prices paid for public procurement of pharmaceuticals below the unit price in the private sector?	Criteria	
		The majority of the unit prices for publicly procured drugs are below the prices in the private sector	
		Total	
		Score*	
49	Are the drug procurement prices made publicly available?	Criteria	
		List is publicly available	
		List contains type of drug, quantity purchased, and price paid	
		Total	
		Score*	
50	Is the procurement conducted using generic names?	Criteria	
		Use of generic names	
		Total	
		Score*	
51	Is the average duration from issuing of tender to delivery of drugs less than 1 year?	Criteria	
		Delivery average less than 1 year	
		Total	
		Score*	
52	Does the procurement unit have an annual audit with published results?	Criteria	
		Annual and published	
		Conducted by an independent auditing firm	
		Total	
		Score*	
53	Are the criteria for adjudication of the tenders included as part of the tender package?	Criteria	
		Clear criteria	
		Criteria is publicly available	
		Total	
		Score*	
54	In the past three years, is the share of drugs purchased through competitive bidding over 80 percent of the total pharmaceutical expenditure?	Criteria	
		Over 80%	
		Total	
		Score*	
Total score for procurement			

* Score = Total/Number of criteria for respective indicator

More than US\$ 3 trillion is spent on health services each year. Such substantial funds are an obvious target for abuse. Transparency International estimates that, on average, 10 to 25% of public procurement spending, including that in the health sector, is lost to corruption. Resources that could otherwise be used to buy medicines or recruit much-needed health professionals are wasted as a result of corruption, which reduces the availability of essential medicines and can cause prolonged illness and even deaths.

In response to this serious problem, WHO launched the *Good Governance for Medicines* project in late 2004. The project's overall goal is to raise awareness of the potential for corruption in the public pharmaceutical sector, and to minimize such corruption by promoting and implementing good governance measures within that sector. Its ultimate aim is to help to ensure that essential medicines achieve maximum impact in terms of improving people's health and well-being.

The countries implementing the *Good Governance for Medicines* project initially conduct an assessment measuring the transparency of national medicines regulatory agencies and public procurement systems. This report summarizes the findings of the transparency assessments in the first four countries to participate in the project, the Lao People's Democratic Republic, Malaysia, the Philippines and Thailand. It provides an insight into the level of transparency and potential vulnerability to corruption in three essential functions of the public pharmaceutical sector, registration, selection and procurement of medicines.

WHO recognizes that corruption is an immense and complex problem, and one that is difficult to tackle. However, the project is growing and helping to increase momentum, as more and more public health colleagues in ministries of health and national medicines regulatory authorities become interested in working on this challenging topic.