Report of the Bi-Regional Consultation on Good Governance for Improved Access to Medicines

MANILA, PHILIPPINES

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<td>Asian Development Bank</td>
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<td>AMR</td>
<td>Anti-microbial Resistance</td>
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<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
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<td>CHAT</td>
<td>Coalition for Health Advocacy and Transparency</td>
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<td>CoC</td>
<td>Code of Conduct</td>
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<td>CSO</td>
<td>Civil Society Organization</td>
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<td>DOH</td>
<td>Department of Health</td>
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<td>EML</td>
<td>Essential Medicines List</td>
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<td>EMP</td>
<td>WHO Essential Medicines and Health Products Department</td>
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<td>Good Governance for Medicines Program</td>
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<td>MoH</td>
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<td>SEAR</td>
<td>South-East Asian Region</td>
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<td>SoP</td>
<td>Standard Operating Procedure</td>
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<td>SSFFC</td>
<td>Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products</td>
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<td>UHC</td>
<td>Universal Health Coverage</td>
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**Background**

The health and pharmaceutical sector with its numerous linkages and actors is particularly vulnerable to losses from corruption in the absence of good sector governance.\(^1\) Corruption and weak governance continue to impede worldwide efforts to increase access to quality assured medicines and therefore to the achievement of global health goals. The problems of access stem from issues of financing, unaffordable pricing, and weak national procurement and supply systems. Addressing these interconnected issues surrounding access to medicines and universal health coverage (UHC) requires good governance\(^2\) in the pharmaceutical sector.

The recent Resolution WHA67.22\(^3\) on access to essential medicines urges Member States to recognize the importance of national medicines policies and their implementation under the concept of good governance to ensure equity in access to medicines and the rational use of medicines. This requires the allocation of resources towards the development, national medicines policies and the strengthening of governance in national pharmaceutical systems.

A bi-regional meeting for representatives from countries from the WHO Western Pacific Region (WPR) and the WHO South East Asia Region (SEAR) was thus held on 9-11 November, 2015 in Manila, Philippines to review and share effective governance practices and strategies for improving access to medicines and to address the implementation of the resolution. Participants included representatives from ministries of health, regulatory authorities, procurement agencies, civil society and pharmacists.

The specific objectives of the meeting were:

1. To advocate for recognition of the importance of effective national medicines policies, and their implementation under good governance;
2. To facilitate the exchange of information and collaboration among Member States on governance best practices;
3. To share experiences with good governance programmes, transparency initiatives and other programmes such the approach of situation analyses of medicines in health care delivery.

This report provides a thematic summary of conference proceedings and discussions. Presentations made at the meeting are available at [www.who.int/medicines/areas/policy/goodgovernance/pharm_sect_critic-uhc](http://www.who.int/medicines/areas/policy/goodgovernance/pharm_sect_critic-uhc)

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\(^2\) Good governance refers to the formulation and implementation of appropriate policies and procedures that ensure the effective, efficient and ethical management of pharmaceutical systems in a manner that is transparent, accountable, follows the rule of law and minimizes corruption.

\(^3\) [http://apps.who.int/iris/bitstream/10665/162868/1/A67_R22-en.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/162868/1/A67_R22-en.pdf?ua=1)
Meeting proceedings

Global and regional perspectives
Good governance has been recognized as critical for the achievement of the Sustainable Development Goals including Targets 3.7 and 3.10 related to access to medicines. Target 16.6: Develop effective, accountable and transparent institutions at all levels and Target 16.7: Ensure responsive, inclusive, participatory and representative decision-making at all levels are particularly relevant for the improving access to medicines.

Access to quality-assured, essential, and affordable medicines is a critical element of UHC and a key leadership priority of WHO. Underlying the concept of UHC is good governance in deciding which services to provide, who to cover, how to reduce out-of-pocket payments and how to fund health care.

The WHO Good Governance for Medicines (GGM) Programme has now been operational for 12 years and extends to 37 countries. The overall objectives of the GGM Programme continues to be to improve good governance, to prevent corruption in the pharmaceutical sector and to contribute to health systems strengthening in countries, focusing on the formulation and implementation of appropriate policies and procedures that ensure the effective, efficient, ethical, transparent and accountable management of pharmaceutical systems. By carrying out an assessment in the first phase of the programme, countries have identified vulnerabilities to corruption and then developed and implemented good governance interventions. Countries across the globe have improved procurement practices; revised pharmaceutical laws and regulations; increased transparency in pricing, registration and licensing and improved management of conflict of interest and accountability.

Member States of SEAR and WPR have undertaken many initiatives towards this end, including carrying out governance assessments and developing frameworks, improving transparency, monitoring indicators for access to medicines, and policy development through multi-stakeholder approaches.

Still, many challenges remain such as how to ensure that national medicines policies are embedded within the national health systems policy framework for UHC, how to obtain political will to implement legislation and commit resources for policy implementation and how to improve enforcement and management capacity to ensure quality and integrity of the supply chain. Other challenges include asymmetries in access to information, poor information systems for monitoring, poor transparency and use of evidence in decision-making processes, such as for benefit package design and selection of essential medicines.

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4 Recent World Health Assembly resolutions: Controls on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFC) (WHA65.19); Strengthen Regulatory Systems (WHA67.20); Access to Bio-therapeutic Products (WHA67.21); Access to Essential Medicines (WHA67.22); Health Intervention and Technology Assessment in support of universal health coverage (WHA67.23); Global Action Plan on Antimicrobial Resistance (WHA67.25)
Multi-stakeholder engagement

A keynote event at the meeting was a presentation and panel discussion by the Medicines Transparency Alliance (MeTA) Philippines. MeTA is a global initiative that seeks to improve transparency and accountability across the medicines supply chain. It functions under the hypothesis that making information transparent and bringing all stakeholders to discuss it will improve access to medicines for all those who need them.

Established in 2007, MeTA Philippines is an alliance of 80 members and organizations and has evolved into a significant advocacy and policy guidance platform. In addition to organizing the first Coalition for Health Advocacy and Transparency (CHAT) and the ETHIKOS Movement for advocacy for ethical medicines promotion, MeTA has also convened various important forums, such as the First Philippine Patients Conference. MeTA Philippines works to collect and analyse robust evidence, disseminate information and facilitate multi-stakeholder dialogue, provide policy or process recommendations, promote action or reform, and raise advocacy and awareness on various topics. The MeTA multi-stakeholder approach has been used to improve medicines promotion regulation, empower patients, mainstream good pharmacy practice, manage the supply chain, and increase SSFFC reporting. The project effectively changed the paradigm of stakeholder engagement particularly through the empowerment of civil society, bringing their concerns into the policy making process.

The panel discussion involved a representative from each sector - government, private and civil society in addition to the MeTA Chair and the MeTA Coordinator.

<table>
<thead>
<tr>
<th>MeTA Philippines panel discussion</th>
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<tr>
<td>Q: What is the role of the Board of Trustees and Council in the different programs of MeTA Philippines?</td>
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<td>A: The Council meets regularly once a quarter to assess accomplishments and discuss priority health issues. Its objective is to link the multi-stakeholder platform with policy makers to promote uptake of decisions. The Board of Trustees also holds bi-monthly meetings to set strategic and policy directions and decide on major organizational and management concerns.</td>
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| Q: How did MeTA choose which stakeholders to engage? What factors led to success? |
| A: MeTA’s objective was to provide access to medicines and healthcare. MeTA decided in the beginning to engage government, civil society, Food and Drug Administration (FDA), Department of Health (DoH), industry, and health professionals. After realizing certain gaps in representation, they engaged patients groups, such as the Philippine Alliance of Patient Organizations (PAPO). The success of MeTA Philippines stakeholder engagement activities can be attributed to the willingness of all stakeholders to come together and commit to MeTA’s principles of transparency. One cannot have progressive dialogue without transparency. The DoH was also receptive to MeTA’s recommendations and the WHO was supportive. |

| Q: For the pharmacist association, what was the role in improving transparency? |
| A: Pharmacists have a key role as healthcare professionals in ensuring the rational use of quality medicines and in providing reliable information to patients and consumers on medication and their care. Transparency enables action by helping policy makers craft more objective and responsive policies related to medication |
management. The role of the Philippine Pharmacists Association was to bring forth accurate information and put forth actionable recommendations - not just comments - for realistic solutions.

Q: How can civil society effectively engage the government? What key recommendations should other governments consider when trying to start a multi-stakeholder platform?

A: In the Philippines, there is a relatively strong private sector. This, notwithstanding, patients and consumers have been active in joining the call for the DOH and its agencies (such as the FDA and PhilHealth) to provide greater access to medicines and healthcare, especially in areas where access is a serious concern. Civil society was also an active participant in lobbying and pushing for the passage of important legislation such as the Cheaper Medicines Act, the Reproductive Health Law, and the Sin Tax Law, among others. A few recommendations based on our experience would be to: 1) Create institutional mechanisms for civil society organizations (CSOs) to engage with the government; Without engagement, no one can participate and nothing can change; 2) Incorporate integrity into the process – civil society must be transparent about their affiliations and funding; 3) Build capacity of civil society to engage with policy makers.

Q: What is the role of research in MeTA?

A: MeTA sets a research agenda, based on a determination of what issues and problems are the most urgent, immediate or pressing, and commissions experts to work on this research to gather evidence for action. Multi-stakeholder dialogue is the most important platform associated with research. The first step is to identify priority concerns. For example, Philippines wanted to involve patients in not only dialogue, but policy making and policy implementation. MeTA Philippines commissioned a study to map patient organizations and identify ways they could be engaged. During the First Philippine Patient Conference, the results of this study were disseminated and discussed with stakeholders. The output was the First Philippine Patients Conference Manifesto, which provided recommendations from those who participated in the discussion. As another example, the Philippines wanted to look into issues related to the framework and procedure for the regulation of medicines promotion. Following discussions on the results of 2 studies related to promotion, MeTA shared the results in a multi-stakeholder Advisory Council forum, specifically proposed models for engaging civil society in pharmaceutical promotion regulation, recommendations and next steps. The advantage of policy dialogue is that MeTA can devise recommendations and immediately push them towards people who can act on them and can then drive the process further.

Q: What are the new challenges facing MeTA?

A: MeTA will soon lose funding and thus sustainability of MeTA’s progress is a key challenge. Additionally, creating a nationally coordinated health care approach is challenging, but necessary to ensure MeTA’s recommendations are implemented.

“It’s OK to disagree and interrupt – this discourse is the very essence of MeTA”...

...“If we don’t participate, we’ll be left out of the conversation.”
Q: What is the added value of MeTA to the DoH?
A: 1) MeTA provided neutral ground for the government to engage with stakeholders; 2) MeTA provided evidence for actions and decisions; 3) MeTA added an element of accountability into government engagement.

Q: What key recommendations should other governments consider when trying to start a multi-stakeholder platform?
A: Create clear rules of engagement. When different types of stakeholders come together to work with the government, conflict of interest must be managed.

The MeTA panel discussion was a highlight of the three-day meeting, and there was keen interest from participants in the multi-stakeholder approach. Most participants agreed that it was important to engage stakeholders, but that it was too difficult in some country contexts particularly with regards to civil society engagement. Despite the complexities and challenges, it was put forth that involvement of civil society was a necessary component of policy processes.

GGM country experience

Malaysia: The GGM Program was introduced in 2004 with the aim of strengthening the health system, preventing corruption, increasing transparency and accountability, and promoting individual and institutional integrity. After conducting a national transparency assessment to identify the laws/policies governing the pharmaceutical sector and the level of transparency and potential vulnerabilities in the pharmaceutical sector, Malaysia introduced several guidelines and trainings to incorporate concepts of good governance into daily operations of health and logistics personnel. Through its National Medicines Policy (MNMP), Malaysia was able to incorporate issues of governance in medicines in 2012. The Malaysian MoH plans to collaborate with other ministries and partners for other GGM initiatives and improve access to medicines through the development of formularies (e.g. the national medicines formularies, updated national essential medicines lists), improvements to the supply chain, monitoring of price information (e.g. Association of Southeast Asian Nations [ASEAN] price database), and enforcing generic substitution. In order to monitor progress of initiatives related to improved access to medicines, Malaysia monitors 105 background, structural, process, and outcome indicators.

Thailand: The GGM Program was introduced in 2004 to improve and enhance the process of drug management through the application of anti-corruption laws, agencies, and mechanisms and the integration of moral values and ethical principles into daily operations in the pharmaceutical sector. Like other countries participating in GGM, Thailand implemented a national assessment to identify vulnerabilities in the pharmaceutical sector and identify ways to strengthen the existing governance infrastructure. Since 2006, Thailand has implemented several initiatives including guidelines development, transparency in pharmaceutical information (e.g. drug

Civil society engagement: country example

China became the 3rd country in the world to develop an essential medicines list (EML) for children. To develop this EMLc, the MoH brought together several multi-stakeholder working groups, including groups to develop guidelines, comprehensive evaluations, training and promotion guidelines, clinical trial guidelines, and an overall list of essential paediatric medicines that would be insured.
price, criteria for selection, registration, procurement, etc.), dissemination of ethical practice information, and assessments to monitor outputs, outcomes, and impacts of GGM initiatives. Though it still faces some challenges in battling innovative corruption techniques, changing organizational structures, and gaps in knowledge management, Thailand gives credit to progress towards UHC and increased access to medicines to its tailored approach, participatory process, and dedicated GGM team.

Information and transparency working group session
For this session, participants divided into groups to discuss common issues regarding transparency and potential solutions. Each group took a different topic to discuss: private sector influence, procurement efficiency, reducing risk of anti-microbial resistance (AMR) and regulatory mechanisms. Group discussions are summarized in Table 1 below.

Plenary discussion included the following points:

- Transparency is a means towards accountability and good governance, but is not an end in itself.
- Public availability of data and disclosure of information supports stakeholder engagement, policy dialogue and increased accountability.
- However, governments must institute discipline or value-based approaches to ensure systemic change to prevent and deter unethical and inefficient practices.
- When data is made transparent, guidelines and limitations for its analysis should also be published.
- Data must be timely, accurate, and available in an easy-to-use and easy-to-understand format if it is to be useful.
Table 1
Summary of information and transparency working group session

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<td></td>
<td>- Divergence of objectives between public and private sector</td>
<td>- Inaccurate quantification and forecasting</td>
<td>- Paucity of utilization information</td>
<td>- Low capacity of regulatory authority for making scientific decisions</td>
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<td>- Tension between trade and public health policies</td>
<td>- Price variances</td>
<td>- Unreliable data from private sector</td>
<td>- Low transparency in making regulatory decisions (e.g. standardization of procedures)</td>
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<td></td>
<td>- Lack of appropriate prescribing and dispensing guidelines</td>
<td>- Poor supplier reliability</td>
<td>- No system for monitoring clinician behaviour</td>
<td>- Lack of accountability (external oversight)</td>
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<td></td>
<td>- No separation between prescribing and dispensing functions</td>
<td>- Delays and bottlenecks in procurement</td>
<td>- Pressures from patients to prescribe antibiotics</td>
<td>- Low enforcement</td>
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<tr>
<td></td>
<td>- Lack of integrated systems between suppliers and prescribers</td>
<td>- Lack of capacity for product testing</td>
<td>- Pharmaceutical promotion and bribing</td>
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<td></td>
<td>- Complicated regulatory processes</td>
<td>- Decentralized procurement causing issues between price and quality</td>
<td>- Issues with enforcing rational antibiotic use</td>
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<td></td>
<td>- Weak enforcement of regulations</td>
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<td></td>
<td>- Low compensation among prescribers/procurement officials</td>
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<td></td>
<td>- Nepotism</td>
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<td></td>
<td>- Weak management in public sector</td>
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<tr>
<td>Recommendations</td>
<td>- Introduce regularly monitored performance indicators</td>
<td>- Monitor consumption and issuance data</td>
<td>- Mandate disclosure of utilization and sales data both for humans and animals</td>
<td>- Involve stakeholders</td>
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<td>- Standardize/Harmonize measurement instruments across the Regions</td>
<td>- Disclose procurement process, timelines, and data used to quantify</td>
<td>- Audit prescription data and treatment outcomes</td>
<td>- Develop criteria for selection of committee members</td>
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<td>- Publish accounting processes</td>
<td>- Outsource responsibility and share</td>
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<td>- Develop standard operating procedures (SoPs) and technical</td>
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and medicines data in a way which can be easily extracted and analysed for comparative analysis
- Disseminate data to stakeholders for external accountability
- Make transparent incentives and interests among officials participating in procuring, prescribing, and dispensing
- Create external bodies to implement and enforce regulatory protocols

| Quality data |
| - Monitor performance of suppliers |
| - Disseminate lists of pre-qualified suppliers, suspended suppliers, and technical specifications |
| - Develop clear process for validating price information |

- Promote health literacy and public awareness among patients about AMR
- Engage pharmacists in educating patients
- Examine anthropological data to change behaviours
- Include AMR in curriculum of professional health education
- Link salary payments to rational use
- Move to computerized monitoring systems

- Publish meeting minutes and regulatory decisions
- Disclose conflicts of interest
- Standardize processes
- Strengthen whistle-blowing mechanisms
- Develop transparent criteria for determining which information is confidential
- Disseminate information among relevant stakeholders
- Collaborate with other regulatory agencies

**Country Examples**
- Mongolia publishes data on medicines imports which can contribute to efficiencies in supply monitoring, utilization, and price negotiations
- Philippines publish the Drug Price Reference Index which provides the range of public procurement prices
- Thailand has a national information centre with price comparisons for antibiotics
- China publishes hospital performance on antibiotic use; pharmacists can review prescriptions; hospitals receive subsidies from the government to account for any profit lost from not prescribing antibiotics
- European countries with small markets and small regulatory capacity collaborate in health technology assessments and other regulatory functions
Integrity

In small groups, participants discussed ways that integrity could be compromised in the public sector and tools that could be used to bolster ethical behaviour. A plenary discussion followed and the following points were raised:

- Integrity and ethics may seem ambiguous in many instances, but ethical actions are clear if there are explicit policies on how to handle potentially unethical situations.
- Ethical behaviour may also be ambiguous when gift-giving or other forms of bribery are socially accepted as ways to cultivate relationships.
- Rather than giving one person full authority, an unbiased committee (chosen through explicit and logical criteria) should make decisions.
- Electronic submissions can also prevent decision tampering.
- Weak systems can sway policy makers into making potentially poor decisions. In the case of procurement, if there are no quantification systems in place, corrupt practice can easily go unnoticed. Similarly, without strict laws and codes of conduct, procurement officers may make decisions that are within the law but that benefit themselves more than the public. Thus, clear codes and sanctions must be in place.
- When faced with ethical dilemmas, individuals may often feel alone or disconnected – making them more vulnerable to partaking in corrupt activities. Strong leadership and/or institutional guidance can support public servants in making appropriate decisions.
- Public awareness of ethical guidelines may deter influencers from tempting public servants.
- Integrity is a two-way street.
- Pharmaceutical companies have an important role to play in preventing unethical behaviour. An example of this was mentioned from the Philippines where pharmaceutical companies can fire representatives that engage unethical marketing practices.
- There are two ways to approach integrity that must be used in combination:
  - Discipline-based approach: everyone who can be corrupt, will be; thus, the system must be protected against corruption;
  - Value-based approach: everyone can improve their own integrity; thus, the system must promote ethical culture within its institutions.
- Countries can utilize both “carrot” and “stick” incentives to stimulate integrity and accountability. In addition to sanctions on those acting unethically, some countries have recognized and commended employees who performed their duties with integrity.
Codes of conduct

Codes of conduct are important for every stakeholder involved in the pharmaceutical sector. In the case of pharmacists, who have interactions with consumers, regulators, manufacturers, and other entities in the health system, codes of conduct are necessary to ensure ethical performance. The International Federation of Pharmacists (FIP) recommends that governments apply laws and practices in the regulatory system to encourage pharmacists and other health care personnel to appropriately manage medicines, minimize “brain drain”, and develop regional collaborations to share technical expertise and disseminate best practices. To this end, FIP and WHO developed Good Pharmacy Practice Guidelines (http://www.fip.org/files/fip/WHO/GPP%20guidelines%20FIP%20publication_final.pdf) covering best practices in dispensing, patient education, therapeutic drug monitoring, medication management, etc.

Ethics trainings and explicit codes of conduct were discussed as useful tools and both have been implemented in many countries in the Regions. Examples include:

- The Philippines: integrity seminars geared towards public officials
- Malaysia: integrity units that bring people together for trainings (e.g. pharmaceutical distribution)
- Papua New Guinea: workshops on leadership training, governance, and values.

Still, trainings are tools and not solutions in themselves. Political will and leadership support for ethical behaviour is needed. A change in mind set is important for understanding that integrity has significant long term benefits for improving system efficiencies, maximizing resources, attracting donors and motivating employees.

Pharmaceutical marketing practice

WPRO conducted a multi-country scoping study on pharmaceutical promotion regulation to identify region-specific issues, needs, and gaps. The countries included were Mongolia, Singapore, Philippines, Australia, New Zealand and Malaysia. In all countries studied, self-regulation was the norm. Stakeholders interviewed in the study highlighted various issues related to pharmaceutical promotion. For example:

- Regulators felt there was no strict monitoring or regulation of medical advertisements.
- Health professionals felt that pharmaceutical promotion was good because they were able to receive information that the government could not provide, but that direct-to-consumer advertisements may be misleading.
- Patient organizations, disease awareness campaigns, etc. are often funded by pharmaceutical companies.

Participants discussed the challenges in combatting unethical medicines promotion including:

Country example

Thailand introduced national ethical criteria on medicinal drug promotion based on WHO guidelines. A memorandum of understanding entails a national code of conduct that must be implemented for procurement officials, pharmacists, pharmaceutical companies, clinicians, etc. Additionally, ethics and codes of conduct when dealing with pharmaceutical representatives are to be included in medical education.
- Regulatory agencies lack the capacity to investigate false advertising claims.
- Industry influence reaches journalists, social media, etc. such that regulation could infringe of free speech.
- Pharmaceutical representatives come in the form of government affairs officers to target regulatory officials, in addition to clinicians.
- Single strategies may be insufficient.

**Accountability**

Accountability and transparency are enabling conditions for UHC. Ethical systems promote social justice and trust among their entities. However, ethics is a result of reasoned value-based judgement that incorporates the idea of equity. Equity is realized in two ways: 1) Horizontal equity, which suggests equal treatment or relatively similar cases and 2) Vertical equity, which suggests unequal treatment of unlike cases. Furthermore, equitable interventions can be based on need, ability to pay, or cost-benefit maximization. Clarity on ethical goals and the resulting equity can help policy-makers reach consensus and make tough prioritization and allocation decisions. While people may never fully agree, they can be fair-minded. Policy-makers, then, can be held accountable for reasonable decisions. In order to enforce accountability, rationales for decisions must be publicly available, relevant in context, and able to be reviewed, challenged, and changed. Additionally, public regulation must be in place to hold systems accountable to these standards.

Public regulations entail the existence of defined standards for behaviour (which are disseminated and made publicly available to concerned stakeholders), the monitoring and assessment of compliance with those standards (which can be made available for public oversight), and the enactment of appropriate consequences if those standards are violated. The penalty must be proportional to the misdeed, but powerful enough to deter those tempted to act unethically (e.g. public blacklisted supplier list). Without tough, independently determined sanctions, the accountability system will be weak and ignored.

**Conflict of Interest (CoI)**

Management of CoI is an important concept in governance, as lack of prevention and regulation of CoI may make individuals/organizations in the public and private sectors susceptible to corruption and unethical behaviour. CoI occurs when an entity has defined duties and either financial incentives to breach their obligations (e.g. stocks in pharmaceutical firm requesting market authorization) or divided loyalties that may cause them to serve other parties in a manner contrary to their defined duties (e.g. physicians that both prescribe and dispense). There are three main ways to manage CoI:

1. Prevention: prohibit entities with CoI from making decisions or mandate disclosure of financial ties.
2. Regulation: Supervise/manage the conduct of entities and limit their discretion in discussions and influence
3. Sanctions: Penalize entities for violating trust and mandate substantial restitution

Discretion is key in the management of CoI. Governments may need to evaluate CoI on a case-by-case basis to determine the frequency of CoI and its seriousness. Ideally, governments should make efforts to eliminate the potential for unethical responses. Decision-making processes, both in selecting decision-makers and the decision themselves, should be structured in a way that criteria are clear and made in a logical, ethical way. Incompatibilities between responsibilities, interests, and incentives must be identified early to avoid bias in decision-making. Sanctions must be strong enough to deter violations of CoI.

Assessment tools

**SEAR Country Situation Analysis**
SEAR Country Situation Analysis was developed in response to the funding situation in SEAR – partners in the region conducted fragmented activities, little sustainable funding was available, national programs needed to respond to AMR, and current medicines monitoring processes were expensive and not operationally useful for national policy making. Thus, SEARO developed a low-cost tool for rapid ‘diagnostic’ appraisal of the national pharmaceutical sector. Data is collected on drug supply, drug selection, drug use, drug regulation, and drug policies to identify problems in the system. Data is then analysed in context so that issues about medicines supply can be linked within the larger environment of health care service delivery. Because the process involves a government team, there is greater political will in the process. After data collection, all information including recommendations and agreements is compiled in a structured report and published online ([http://www.searo.who.int/entity/medicines/country_situational_analysis/en/](http://www.searo.who.int/entity/medicines/country_situational_analysis/en/)). Data can be matched with interventions and situations to assess the functionality of the health system and then the data can be disseminated to stakeholders who can take action. Any country can implement a situation analysis, so long as it can nominate public officials to work with WHO to carry out the assessment. In general, findings showed under-resourced and manual drug supply systems (leading to issues of improper quantification and stock-outs), fragmented drug policies, understaffed drug regulatory authorities, poor AMR stewardship, and low availability of medicines at the primary care level because non-communicable diseases are more often treated at other levels of the health system.

**WHO GGM Transparency Assessment Tool**
The GGM Transparency Assessment Tool for the pharmaceutical sector has been used in 37 countries over the past 10 years. The objective of the tool is to provide countries with a diagnostic of the level of transparency and
vulnerability to corruption in the procedures and structures of eight core functions of the pharmaceutical sector (registration, licensing, inspection, promotion, clinics trial oversight, selection, procurement, and distribution). The assessment consists of a desk review to determine the existence of norms and standards, and key informant interviews to measure perceptions. The current version of the tool has been valued in countries, but is lengthy and has a complex scoring methodology. WHO has thus undertaken a revision of the tool to simplify the methodology and to include an assessment of accountability. The conference participants reviewed sections of the first draft revision and provided important feedback which will be used for the next revision.

**Partners and civil society perspectives**

**Asian Development Bank (ADB)**

The ADB has committed to increasing health sector lending to USD$1 billion by 2020, primarily focusing on projects and knowledge creation and dissemination related to UHC and the strengthening of health systems infrastructure, governance, and financing ([http://www.adb.org/documents/adb-operational-plan-for-health-2015-2020](http://www.adb.org/documents/adb-operational-plan-for-health-2015-2020)). Specifically related to improving access to medicines, ADB is strengthening the capacity of regulatory agencies in Asia to support regulatory convergence and harmonization, to participate in WHO’s Global Surveillance System of SSFFCs, and to conduct post-marketing surveillance of pharmaceuticals particularly for malaria and communicable diseases. To this end, ADB and partners are working with CoRE, the Centre of Regulatory Excellence established in Singapore in 2014, which seeks to build capabilities amongst mid- and senior-level regulatory staff and executives, serve as a platform for multi-stakeholder collaboration and coordination in regulatory science, and promote regulatory leadership and encourage policy innovation across the Asia-Pacific. CoRE ultimately aims to ensure that patients have timely access to safe, effective and high quality therapeutic products via regulatory excellence. Currently in Phase 1 of the their project with ADB support, CoRE is working with regulatory agencies in Cambodia, Laos, Myanmar, Thailand, and Vietnam to conduct a capacity and needs assessment and to develop a work plan to strengthen national regulatory authorities (NRAs) on regulatory issues for malaria and other communicable diseases. Phase 2 of the CoRE project will focus on helping countries build capacity to regulate and monitor pharmaceuticals related to communicable diseases and improve the speed and quality of registration of these products.

**UNDP’s Global Anti-corruption Initiative (GAIN)**

UNDP’s GAIN proposes an integrated, sectoral approach on anti-corruption work in order to strengthen systems, institutions, and civic engagement for better management and delivery of public resources and services. GAIN incorporates elements of policy and program support, internal/external capacity development, advocacy and awareness, and knowledge management in its tailored activities against corruption. Interdisciplinary in its activities with governments, civil society, community networks, and media, GAIN’s consultations focus on specific sectors to assist countries in developing targeted guidelines and tools for a nuanced approached in tackling corruption. Additionally, GAIN also utilizes a results-based approach to anti-corruption activities in which it produces knowledge, specific to the sector, holds trainings and workshops to strengthen collaboration between anti-corruption experts and sector experts, develops tools to assess corruption risks, designs plans based on identified risks, assists countries in piloting solutions against corruption, and finally evaluates the impact of the anti-corruption efforts to disseminate lessons learned and further the knowledge base for
interventions. Jordan, Ghana, Chile, Kosovo, and Serbia have already introduced plans and platforms based on GAIN consultations. UNDP released a publication on key methods, tools, and practices to fight corruption in the health sector (http://www.undp.org/content/undp/en/home/librarypage/democratic-governance/anti-corruption/fighting_corruptioninthehealthsector.html) based on GAIN initiatives. Key findings from GAIN projects include:

- Health policy goals should include anti-corruption considerations.
- There is no ‘one size fits all’ approach to combating corruption in the health sector.
- More than one anti-corruption intervention should be employed to deal with one risk.
- Prioritization is essential: based on evidence, governments and others involved in health projects and programming should prioritize areas of the health system that are most susceptible to corruption and implement appropriate interventions.
- Prevention is the best strategy: therefore, it is best not to wait for corruption to happen before beginning to deal with it. Numerous empirical diagnostic tools should be employed.
- Partners with experience in implementing anti-corruption strategies and tactics should be identified for technical support.
- Broad participation in health policy and planning helps.
- Good behaviour should be rewarded, and bad behaviour punished.

Representatives from civil society spoke about different initiatives in their countries.

**Philippines**

Stronger patient advocacy has recently emerged in the Philippines, along with calls for government to provide resources to address their concerns. MeTA and similar multi-stakeholder councils have provided the platform for patients and patient organizations (1) to articulate their needs and concerns; and (2) to be engaged and consulted on policies and programs affecting their health and care.

Advocacy by patient organizations has influenced the implementation of medicine access programs by the National Government. For example, a lobby for making paediatric cancer drugs available prompted the DOH to cause the importation of such medicines that were subsequently distributed through specific access sites. Additionally, this program provided the evidence that prices of cancer drugs were from 500-1000% higher than in other countries, leading the government to look into this problem more closely.

Civil society and patient organizations comprise an important sector in the health dialogue. To foster patient-centred care, this sector must be organized, capacitated and resourced to enable it to reach its full potential as an active participant in the development of an effective health system.

**Transparency International Bangladesh (TIB)**

TIB conducted a study in 2014 to identify governance challenges in Bangladesh’s Drug Administration capacity to monitor and regulate the pharmaceutical sector and to provide recommendations to improve governance for medicines. The study identified a number of challenges including: a lack of clear regulatory guidelines across
various points of the supply chain; ambiguous criteria for selection and the formation of committees, capacity constraints across the sector, lack of transparency in public processes, and lack of accountability among staff. Following the study, TIB presented a set of recommendations that were received positively by policy makers. These recommendations included the need to update laws and policies to address contemporary challenges, the addition of legal professionals in the drug authority, improvements to public transparency (e.g. clear roles, updated websites, uniform reporting), an increase in staff, introduction of positive and negative incentives to reduce corrupt practices.

Next steps

In discussing the way forward following the meeting, participants concluded and proposed the following:

- Continue efforts to improve good governance in countries;
- Integrate and institutionalize good governance practices throughout the pharmaceutical sector;
- Continue to exchange experiences in best practice;
- Engagement with CSO is needed;
- Build the evidence on the extent of corruption in the pharmaceutical sector;
- Address corruption at the highest levels;
- Carry out advocacy at the country level;
- Develop country-specific road maps as part of the national policy and planning process to ensure accountability, improve access to medicines, and ultimately advance the UHC agenda;
- Build political will across multiple sectors;
- Commit sufficient funding to implement policies;
- Establish transparent mechanisms to monitor the progress and evaluate the impact of policies surrounding UHC, including those related to improved access to medicines;
- Support needed to provide governments with guidance on how to include CSOs in regulatory and governance activities;
- A web site with documentation for best practices in medicines management would be useful.

In addition, WHO will:

- Support capacity for improving governance in countries;
- Continue the revision process for the GGM assessment tool;
- Coordinate the different tools for assessments of usage, processes, outcomes, etc.;
- Continue to support countries to build capacity and to make progress in the area of governance.
### AGENDA

#### Monday 9 November

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>8:30-9:00</td>
<td>Registration</td>
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<tr>
<td>9:00-9:15</td>
<td><strong>Welcome messages</strong>&lt;br&gt;<strong>Kees de Joncheere, Director</strong>&lt;br&gt;<strong>WHO Department of Essential Medicines and Health Products</strong>&lt;br&gt;<strong>Kenneth Hartigan-Go, MD Department of Health Philippines</strong></td>
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<tr>
<td>9:15-9:30</td>
<td><strong>Introductions</strong></td>
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<td>9:30-9:45</td>
<td>Administrative announcements / Introduction to the agenda and meeting objectives</td>
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<tr>
<td>9:45-10:00</td>
<td><strong>Group photo</strong></td>
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<tr>
<td>10:00-10:30</td>
<td>Coffee break</td>
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<tr>
<td>10:30-11:10</td>
<td><strong>Global and Regional Perspectives</strong>:&lt;br&gt;10 Years of Good Governance for Medicines, Deirdre Dimancesco, Technical Officer, Department of Essential Medicines and Health Products&lt;br&gt;Situation analysis in SEAR, Kathleen Holloway, Regional Advisor SEARO&lt;br&gt;Access to medicines in WPR, Klara Tisocki, Regional Advisor WPRO</td>
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<tr>
<td>11:10-11:40</td>
<td><strong>Experience with Good Governance for Medicines in countries</strong>&lt;br&gt;<strong>GGM programme in Malaysia, Kamarunnesa Binti Mokhtar Ahmad, Deputy Director, Division of Pharmacy Practice and Development, Ministry of Health Malaysia</strong>&lt;br&gt;<strong>GGM programme in Thailand, Chanvit Therathep, Inspector General, Ministry of Health, Thailand</strong></td>
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<td>11:40-13:00</td>
<td><strong>Multi-stakeholder policy dialogue</strong>&lt;br&gt;Presentation: The Medicines Transparency Alliance Philippines, Cecilia C. Sison, Country Coordinator, MeTA Philippines&lt;br&gt;Panel discussion:&lt;br&gt;<em>Mr Roberto Pagdanganan, MeTA Philippines Chair</em>&lt;br&gt;<em>Dr Ana Melissa S. Guerrero, Programme Manager, Representative for the National Center for Pharmaceutical Access and Management Department of Health</em>&lt;br&gt;<em>Mr Josefino de Guzman, President, Psoriasis Philippines, Representative, Philippine Alliance of Patients with Chronic Illness (PAPCI)</em>&lt;br&gt;<em>Ms Leonila M. Ocampo, RPh, MS, Board Director/Past President, Philippine Pharmacists Association, President, Asia Pacific Institute for Medication Management, Inc.</em>&lt;br&gt;Facilitator: <em>Mr Roderick Salenga, National Professional Officer, WHO Country Office Philippines</em></td>
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<tr>
<td>13:00-14:00</td>
<td>Lunch</td>
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### Tuesday 10 November

<table>
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<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:30-8:45</td>
<td>Review of Day 1</td>
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<tr>
<td>8:45-10:15</td>
<td><strong>Integrity</strong> : Workshop Session</td>
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<tr>
<td>10:15-10:45</td>
<td>Coffee Break</td>
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<tr>
<td>10:45-11:30</td>
<td><strong>Experience with implementing codes of conduct for public sector employees and pharmacists</strong></td>
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<td></td>
<td>Woorasuda Yoongthong, Senior Pharmacist, Bureau of Drug Control, Ministry of Health, Thailand</td>
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<td>John Jackson, President International Pharmaceutical Federation (FIP)-Western Pacific Pharmaceutical Forum, Discussion</td>
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<tr>
<td>11:30-12:15</td>
<td><strong>Codes of conduct for public sector employees</strong>: Small group discussion session</td>
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<td>12:15-13:15</td>
<td><strong>Accountability</strong></td>
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<td>Accountability and Universal Health Coverage (UHC), Vivian Lin, Director Department of Health Systems</td>
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<td></td>
<td>Ethical Considerations to Guide Accountable Policy Decisions, Calvin Ho, Centre for Biomedical Ethics, Yoo Ling School of Medicine, National University of Singapore</td>
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<td>Achieving accountability in the pharmaceutical sector: A practical approach, Anne Paschke, WHO Consultant</td>
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<td>13:15-14:15</td>
<td>Lunch</td>
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<td>14:15-15:30</td>
<td><strong>Pharmaceutical marketing practices</strong></td>
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<td>Presentation: Multi-country review of marketing regulations , Klara Tisocki, Regional Advisor WPRO</td>
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<td>Facilitated discussion: Tim Reed, Executive Director, Health Action International</td>
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<td>15:30-16:00</td>
<td>Coffee break</td>
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<tr>
<td>16:00-17:00</td>
<td><strong>Partner initiatives in good governance and anti-corruption in the pharmaceutical sector</strong></td>
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<td>Presentation: UNDP Global Anti-corruption Initiative (GAIN), Israel Marañón De Pablo, Anti-Corruption Analyst, Bureau for Policy and Programme Support, UNDP Global Centre for Public Service Excellence</td>
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<td>Presentation: Challenges of Good Governance in Drug Administration in Bangladesh, Mohammad Rafiqul Hassan, Director Research &amp; Policy, TI Bangladesh</td>
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<td>Presentation: Regulatory harmonization and the work of CoRE, Douglas Ball, RECAP Regulatory Specialist, ADB Consultant</td>
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<tr>
<td>17:00-18:00</td>
<td><strong>Conflict of interest</strong> : Small group discussion</td>
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<tr>
<td>18:00</td>
<td>Departure for dinner hosted by Government of the Philippines</td>
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# Wednesday 11 November

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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| 8:30-9:45| **Conflict of interest**  
Presentation and question and answer session, Marc Rodwin, Professor of Law, Suffolk University Law School Boston, MA |
| 9:45-10:05| **Country experiences**  
Lobbying for patient rights in the Philippines, Carmen Auste, Managing Director, Cancer Warriors Foundation, Global Chair, Childhood Cancer International  
Challenge and exploration of Children’s access to medicines: Experience in China, Dr Lingli Zhang, Chief Pharmacist and Director of the Pharmacy department, West China Second University Hospital, China |
| 10:05-10:30| Coffee break |
| 10:30-13:00| **National assessment of transparency and accountability in the pharmaceutical sector**  
Presentation: Anne Paschke, WHO Consultant  
Parallel workshop sessions on using the new assessment tool: desk review/key informant interviews |
| 13:00-14:00| Lunch |
| 14:00-15:00| **National assessment**  
Workshop session: using assessment results for priority setting |
| 15:00-15:30| Coffee break |
| 15:30-16:30| **Next steps and closing session** |
“Bi regional consultation on good governance for improved access to medicines”
9 – 11 November 2015, Manila, Philippines

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9 – 11 November 2015, Manila, Philippines

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