SIAPS TECHNICAL BRIEF

Developing Better Terms of Reference to Improve the Performance of Pharmaceutical Sector Committees: Case Studies from South Africa

The **Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program** works to ensure the availability of quality pharmaceutical products and effective pharmaceutical services through systems strengthening approaches to achieve positive and lasting health outcomes. SIAPS is funded by the US Agency for International Development (USAID) and is implemented by Management Sciences for Health (MSH).

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Background

South Africa, with its population of 55 million people,[1] continues to be the country with the largest number of people living with HIV, estimated at 7 million in 2015. In 2016, an estimated 3.5 million people were receiving antiretroviral therapy (ART).[2] The September 2016 introduction of the universal test and treat policy, which provides for immediate access to ART for all who test positive for HIV, has significantly increased the number of people on ART. There is also a high burden of tuberculosis (TB) in the country, with increasing numbers of patients diagnosed with multi- and extensively drug-resistant TB. It is estimated that approximately 60% of individuals with TB are also infected with HIV.[2] Furthermore, many people live with non-communicable diseases (NCDs) such as hypertension and diabetes. In 2013, more than 50% of deaths and 33% of the burden of disease in South Africa were attributable to NCDs.[2] The government is taking steps to reduce the burden of disease by encouraging the reduction of risk factors and promoting early diagnosis. The provision of quality health care services, which are crucial for preventing and treating communicable and non-communicable diseases, depends on the ready availability of affordable medicines, diagnostics, and medical supplies of assured quality. In addition, medicines and other pharmaceutical products must be used appropriately to achieve desired health outcomes.

In the pharmaceutical sector, governance is a key enabler for ensuring that the medicines needed to provide health services "travel from the laboratory bench to the patient's bedside."[3] Although governance has been defined in numerous ways, the definition of governance as "the process of decision making and the process by which decisions are implemented (or not implemented)" put

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forward by the United Nations Economic and Social Commission for Asia and the Pacific (UNESCAP)[4] is especially relevant in the pharmaceutical sector with its multiple, interdependent processes and decision points. Various players, including regulatory bodies, national and provincial health departments, and health care professionals, make decisions that impact whether patients are able to access the medicines they need to prevent or treat disease and whether these medicines are safe, effective, and of good quality. Decisions include which medicines should be registered in the country; which should be selected for inclusion in essential medicine lists and standard treatment guidelines; what financial resources will be used to purchase medicines; the sources from which medicines will be procured; how distribution will be organized; who can prescribe, dispense, or sell medicines; and where they can be sold.

Recognizing the importance of strengthening pharmaceutical sector governance, the US Agency for International Development (USAID) included governance as a key results area in its Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, which is implemented by Management Sciences for Health (MSH). The program works to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. In many countries, SIAPS' support has included technical assistance in establishing and optimizing governance structures to support appropriate decision making and the provision of effective oversight in the pharmaceutical sector.

In South Africa, there are numerous governance structures, including councils and committees operating at national, provincial, district, and facility levels that make crucial decisions about selection, procurement, distribution, and use of medicines, diagnostics, and other pharmaceutical products. A challenge commonly encountered is that critical committees either do not exist, leaving decision making to individuals, or where the committee is in place, it does not function optimally. For example, there may be no committee (such as a Pharmaceutical and Therapeutics Committee [PTC]) making decisions about which medicines should be used in a hospital, leading to over-expenditure and inappropriate use of medicines. In other cases, the PTC is in place, but has poor representation of key stakeholders, meets infrequently, or accomplishes little. One of the underlying causes of poor functioning of committees is the absence of or weak terms of reference (TOR). The development of TOR is also an important key step in establishing any new committee.

Strategic Response: Development of a TOR Guidance Document

In 2015, the Affordable Medicines Directorate (AMD) of South Africa's National Department of Health (NDOH), requested assistance from SIAPS in strengthening the TOR of several national committees, including those involved in selection of medicines for inclusion on the National Essential Medicines List (NEML), the contracting of service providers, and the licensing of pharmacies. In response, SIAPS developed a TOR guidance document that can be used in the development or review of TOR for all types of pharmaceutical sector committees. The purpose of this brief is to share the guidance document and the processes SIAPS and their counterparts followed to develop new and revise existing TOR for three different pharmaceutical sector committees in South Africa.

Importance of Robust TOR

The TOR defines the roles and responsibilities of any governance or management structure and provides a framework within which it must function. It also reflects the purpose, broad objectives, membership, and method of functioning of the body in a way that can be understood by all members and external stakeholders. In simple terms, the TOR describes **what** must be done, **who** is responsible for carrying out identified functions or tasks, **how** the structure or committee will function, and **how often** it will meet. The TOR is also a useful tool for communicating information about the committee to external stakeholders. A robust TOR helps delineate the work of governance structures from those of management and can encourage key actors to participate in the committee by clarifying expectations. In addition, it can also help to reassure political leaders and funders that resources, such as pharmaceutical budgets and medicines, are governed well.[5]

Figure 1. UNDP characteristics of good governance[6]

The TOR sets the foundation for good governance in the functioning of the structure or committee. UNDP has proposed principles of good governance (figure 1). In line with these principles, the TOR should—

- Enshrine a **strategic vision** by providing a clear description of the purpose and objectives of the committee
- Describe how relevant stakeholders are either represented on the committee or have a mechanism of providing input to facilitate **participation**
- Promote **transparency** by detailing how committee processes will work and decisions will be made, documented, and communicated to those affected
- Describe how decision making will occur in the committee with an emphasis on **consensus-orientation**; guidance must also be included on action to be taken when consensus is not reached
- Ensure that where the committee is established in accordance with an act or regulation, this is clearly stated and that the committee operates in accordance with the **rule of law**
- Support **equity** by including clauses that ensure that members of the committee representing different stakeholders are treated in the same way and have an equal opportunity to contribute to decision making; likewise, external stakeholders who are directly affected by decisions of the committee must be treated fairly
- Describe how committee processes will work to make **efficient** use of resources and how the committee will function in order to be **effective** and produce results that meet the needs of people served
- Where appropriate, include timeframes for actions to be performed and responses provided to stakeholders to facilitate **responsiveness**
- Mention mechanisms for holding the committee and its members **accountable** for actions of the committee

In addition the TOR must promote **integrity** of both the committee and its members by making rules about confidentiality and the declaration and management of conflicts of interest (COIs).

TOR Guidance Document: Development Process

An initial desk review of the existing TOR of various committees that fall under the purview of AMD revealed differences in approach, content, and level of detail. To support counterparts to undertake TOR revisions independently in the future, SIAPS identified the need for a guidance document that could be used to develop or review the TOR of any pharmaceutical sector committee, either in South Africa or elsewhere. To develop the TOR guidance document, SIAPS with input from AMD staff—

- Reviewed the differences and similarities in existing TOR
- Developed a simple set of guiding principles that could be applied in the development or review of TOR for any committee
- Identified the main headings that should typically appear in any TOR and listed these in a logical order
- Developed suggested content that could be included under each heading; in some instances, examples of wording that could be used were also included
- As far as possible, used simple and clear language to avoid ambiguities or inconsistencies

The resulting *Guidelines for the Development of the Terms of Reference of a Committee* (the guidance document) is attached as annex A at the end of the document. A schematic representation of the framework is provided in figure 2.

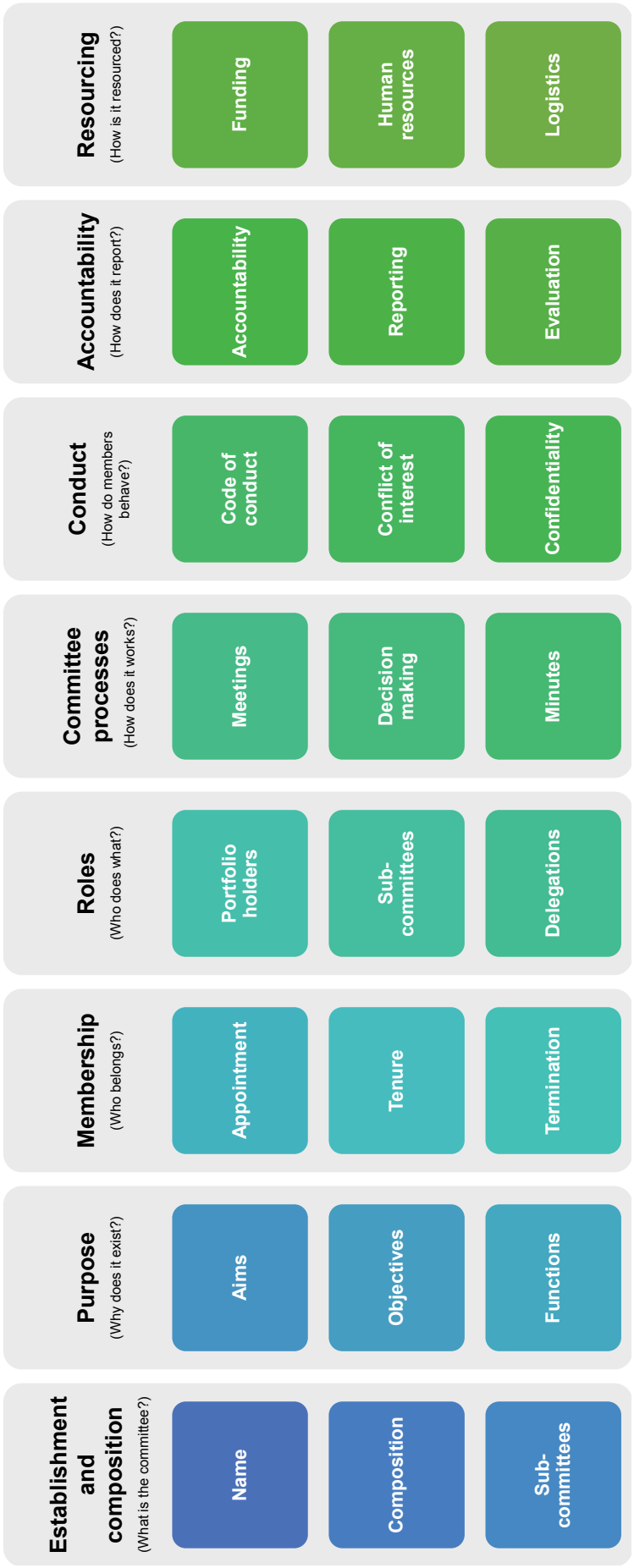

Figure 2. Schematic representation of TOR framework

SIAPS subsequently worked with AMD staff to review and revise the TOR of one of the committees involved with making decisions on the awarding of national contracts for the supply of medicines and to develop the TOR for a new national forum to promote transparency about medicine availability in both the public and the private sectors. SIAPS also worked with the Department of Correctional Services (DCS) to develop the TOR of PTCs in six regions in the country.

Case Study 1: Revising the TOR for Committees Involved in Decision Making on the Awarding of Medicine Contracts

Background

The role of South Africa's NDOH is that of policy making, coordination, monitoring, and providing oversight. The nine provincial Departments of Health provide health services, with each province purchasing medicines and managing its own budget for medicines. Government uses an open tendering process prescribed in the Public Finance Management Act 1 of 1999 (PFMA) to procure medicines, diagnostics, and other medical products. Regulations to the PFMA set out the rules for the tendering process, including how specifications should be determined, tenders advertised, bids evaluated, and contracts awarded. In accordance with international guidance and best practice, the tendering process must be based on the principles of fairness and transparency and should promote competition and cost-effectiveness. The regulations require the establishment of three committees with distinct functions, namely a specification committee, an evaluation committee, and an adjudication committee. The establishment of three committees with different roles and responsibilities separates functions and promotes good governance.

Recognizing the expertise needed in the process of tendering and awarding contracts for medicine, the NDOH decided to manage medicine tenders at the national level. NDOH thus established two committees within the AMD—the pharmaceutical specification and evaluation committees. Because all provinces participate in the national contracts, each province is represented on both committees. A third committee, the NDOH departmental adjudication committee, which includes high-ranking NDOH officials, makes recommendations to the director general (DG) on the awarding of contracts.

The function of the specification committee is first to ensure that all products required are included in a tender and that specifications are clear and comprehensive, but sufficiently generic to allow maximum competition between pharmaceutical companies. In addition, the specification committee reviews and agrees on the items to be advertised on tender, the quantities needed, and the conditions of contract to be applied post-award. Once the tender has been advertised and bids received, the evaluation committee reviews bids for compliance and compares prices. The committee then makes recommendations on awarding of contracts to the adjudication committee, which makes the final recommendation to the DG. Contracts are then signed between the DG and the successful bidder for the supply of each product. The process is depicted in figure 3. Each of these committees makes important recommendations that influence which products and how much of each is needed, the company to whom a contract will be awarded for supply to the whole country, and the price to be paid.

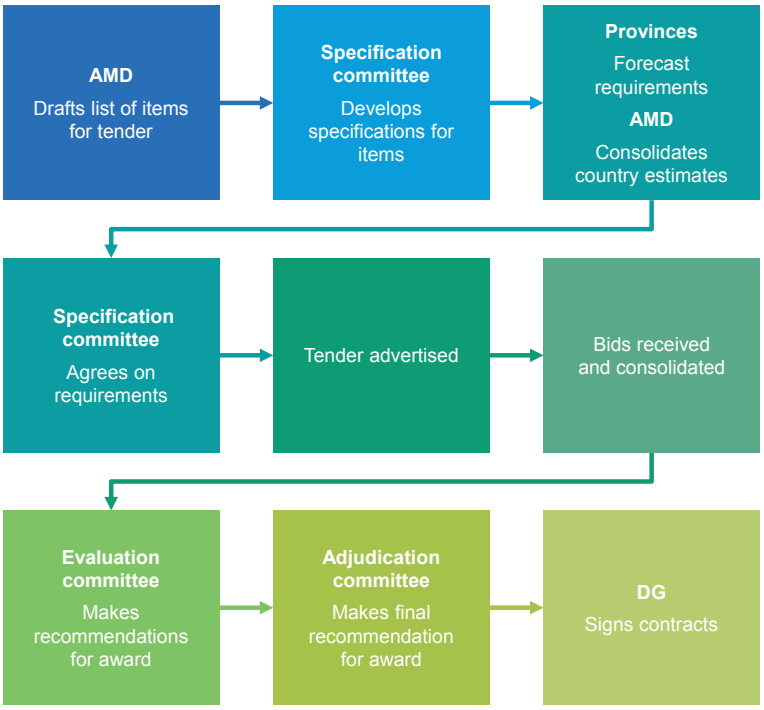

Figure 3: NDOH contracting process for medicines

TOR Review Process

SIAPS was asked to provide support to improve and strengthen the TOR of the specification committee and the evaluation committee. Although both committees were functioning well and had TOR documents, there was a need to better align and delineate the functions of these committees, better integrate the principles of good governance, and strengthen adherence to best practice.

Here we describe the process used for the revision of the TOR of the evaluation committee. We started by using the framework in the guidance document to analyze the existing TOR and identify areas for improvement.

The team consisting of SIAPS and AMD officials—

- Prepared a table that mapped each component of the TOR against the framework in the guidance document
- Identified gaps, discussed the relevance thereof, and added content as needed
- Addressed overlaps and strengthened the flow and language of the TOR
- Dropped non-applicable headings only when it was confirmed that all key aspects of the committee's work were covered, and finally converted the table into text

In addition to guiding their thinking and helping them to work systematically, the team found that using the generic framework was a straightforward way to identify areas for improvement. The team strengthened the sections in the existing TOR dealing with the composition and appointment of members by making it clear how and by whom members are appointed. The revised TOR also clarified which of the people who attend meetings were actually members of the committee with voting rights and who were members of the secretariat providing technical and administrative support. Provision was also made to deal with situations when a member is unable to attend a meeting as well as termination of membership, for example, in circumstances where a member no longer holds the position by virtue of which he or she was appointed. The team decided to retain some basic principles such as meeting procedures, even where these seemed obvious. It was thought that this would provide guidance to members and support synergies in the way that the various committees operate. More specific detail was added as to who is responsible for compiling and sending out agendas and minutes and the timeframes in which this must be done.

> "Given the number of committees that are managed by the Affordable Medicines Directorate, having a systematic way of developing the TOR for each of these has been very effective. There is no ambiguity among members about any issue that may potentially have been a problem."
>
> Ms. Khadija Jamaloodien, Director of AMD

After input had been obtained from various stakeholders, including AMD officials, and incorporated, the revised TOR for the evaluation committee were presented to the committee for final input and comment prior to sign-off by the DG.

Results and Next Steps

The approach used was deemed to be helpful by the staff of AMD. Through this review, members of the committees and the AMD staff became clearer about expectations and their roles and responsibilities, the underlying reasons for processes, and the importance of separation of functions. Furthermore, the roles of the committees were better delineated. Gaps found during the review of the TOR were addressed. The new TOR were put into use at the end of 2016.

Case Study 2: Establishing a Forum to Promote Transparency and Stakeholder Engagement

Background

In addition to optimizing the functioning of committees responsible for making technical decisions, it is also important to ensure that bodies and committees that engage stakeholders and provide oversight are in place and function well. This section provides an example of SIAPS technical assistance to South Africa's NDOH to help establish a multi-stakeholder forum.

Shortages and stock-outs of medicines and health commodities in both the public and the private sectors may occur because of various factors affecting multiple processes, and involving different stakeholders. Factors may include delays in the registration of products, problems in the manufacturing process, inadequate forecasting and demand planning, sub-optimal management of stock, and failure to use medicines appropriately. Because of the large number of stakeholders involved, it is important to involve them in the design of improvement strategies and gain their commitment for successful implementation. Increasingly, civil society organizations play an oversight role in highlighting challenges with medicine availability, particularly at health facilities.

The establishment of a multi-stakeholder forum was included as an objective in the NDOH Annual Performance Plan for 2016.[2] This thinking is in line with the hypothesis put forward by Medicines Transparency Alliance who suggest that "getting information about the medicine supply chain out in the open and having it analyzed and discussed by three major stakeholder groups—the government, private sector, and civil society—will lead to a better understanding of the problems, greater incentives to pioneer change, and greater responsibility and accountability upon those needed to instigate these changes."[7]

The purpose of this new governance structure—the Forum to Promote Transparency and Multi-Stakeholder Engagement Regarding Medicine Availability (the forum)—is to improve availability and equitable distribution of medicines through enhanced transparency, efficiency, responsiveness, and accountability in the supply chain. The forum is intended to provide structured opportunities for stakeholders to share information about medicine availability, including potential shortages, discuss and acquire a deeper understanding of challenges faced, contribute to identifying priorities and solutions, and participate in policy making processes.

TOR Development Process

SIAPS worked with the NDOH to prepare a draft TOR for the forum and helped facilitate a workshop in September 2016 with stakeholders to discuss and plan for the forum's establishment. The first step was a literature review of similar fora operating in other countries and other contexts.[7] The next step was a mapping of stakeholders to identify key groups that were subsequently invited to participate. SIAPS then worked with the NDOH staff to craft the forum's TOR by using the framework in the guidance document as a reference. As the establishment of such a forum is a new concept in the country, careful attention was paid to providing sufficient detail in the TOR on the goals and expectations of the forum to encourage participation of stakeholders.

The subsequent workshop was attended by representatives from different sectors including representatives of the NDOH, provincial Departments of Health, the Department of Trade and Industry, the Department of Science and Technology; the South African Military Health Services, various regulatory bodies including the Medicines Control Council and the South African Pharmacy Council, professional associations, manufacturers, private health care providers including pharmacies and private hospitals, medical benefit organizations, civil society, development partners, and donors. The objectives of the workshop were to explain the rationale behind the establishment of the multi-stakeholder forum, share information on reforms underway to improve medicine availability, discuss the draft TOR, and facilitate stakeholder participation.

Figure 4: Example of a vision for access to medicines developed by one of the teams during the forum consultation workshop

During the workshop, participants worked in teams to literally draw their vision of a desired future state of access to medicines (figure 4). This approach helped stakeholders from different sectors and organizations develop a shared vision, appreciate the need to work together, and clarify the purpose of the forum. Participants also discussed their role in making medicines available, and agreed that insufficient dialogue was taking place between the various groups. The draft TOR were presented at the workshop and discussed. Participants stressed that because of the diversity of the stakeholders, transparency in the establishment and functioning of the forum, including selection of members, effective and equitable participation, and accountability of representatives to the constituencies represented were key to success. Both the concept of the forum and the draft TOR were well received by participants. Following the workshop, organizations were given the opportunity to provide written feedback on the TOR, after which it was finalized.

Results and Next Steps

This systematic and consultative process, which included meticulous attention to facilitate active stakeholder engagement, contributed toward developing a sound TOR for the forum. The workshop also served as an initial orientation to the forum and provided an opportunity for stakeholders to develop and agree on a clear vision of what they want it to achieve. Furthermore, because stakeholders were engaged in developing the TOR, they are already familiar with the document and have a vision of how the forum will function. Despite the potential challenges in setting up such a structure with representation of a diverse group of stakeholders, attendees demonstrated a willingness to work together toward a common goal and to establish a platform where challenges around medicine availability can be identified and addressed. The NDOH invited organizations to nominate representatives to the forum by the end of January 2017 after which formal appointments would be made. The first meeting of the forum was scheduled to take place in 2017.

Case Study 3: Strengthening Pharmaceutical and Therapeutics Committees to Improve Medicine Selection and Use in the Department of Correctional Services

Background

South Africa has 243 correctional centers in 6 regions—Gauteng; Eastern Cape (EC); Western Cape (WC); KwaZulu-Natal (KZN); Limpopo, Mpumalanga, and North West (LMN); and Free State and Northern Cape (FS/NC). In the financial year 2015/16, the average number of inmates within the DCS was 159,331.

The DCS is faced with numerous challenges in providing health care in correctional facilities to inmates, awaiting trial detainees, and cared-for children in its custody. A particular challenge is that inmates may receive health care services from either the public or the private sector prior to imprisonment,

and they may move in and out of the correctional system. The DCS has a responsibility not to interrupt treatment of patients under its care, regardless of whether the medicines were initiated in the public or private sector. DCS thus faces a significant challenge in deciding which medicines should be stocked and making decisions about switching therapy to effective alternatives available in the DCS. Also important is improving the appropriate use of medicines across the DCS. The TOR guidance document was also used to assist the DCS in developing TOR for PTCs as a first step to establishing or improving the functioning of existing committees in all six regions.

TOR Development Process

In 2015, recognizing the role of PTCs in promoting equitable access to safe, effective, and affordable medicines, SIAPS was asked to provide assistance to address DCS' unique set of challenges. Although there were PTCs in some regions, the extent of their functionality was unclear. As a first step, SIAPS provided training for DCS personnel on PTCs to help them establish fully functional PTCs in all regions. DCS and SIAPS agreed that the desired outcome of the training workshop was to improve understanding of the roles, functions, and structure of PTCs and establish standardized draft TOR for PTCs for the six regions. The workshop, held in November 2015, was attended by the director of Health Services, the deputy director of Pharmaceutical Services, and 32 representatives from all regions, including officials responsible for implementing PTCs.

Working in regional teams, the participants drafted TOR for the PTC in their region. During this process, the teams realized that only three regions (Gauteng, KZN, and WC) had a TOR for their PTC, with Gauteng's being the most robust. Each team prepared a draft TOR for their regional PTC using the framework in the guidelines and the Gauteng TOR as a benchmark. After the workshop, regional representatives consulted with key stakeholders to fine tune the TOR for their particular region and submitted it for review. SIAPS worked with the deputy director of Pharmaceutical Services to review and standardize the six TOR as far as possible. The draft TOR were then submitted to the national commissioner for Correctional Services who is responsible for recommending policies to the relevant minister (figure 5).

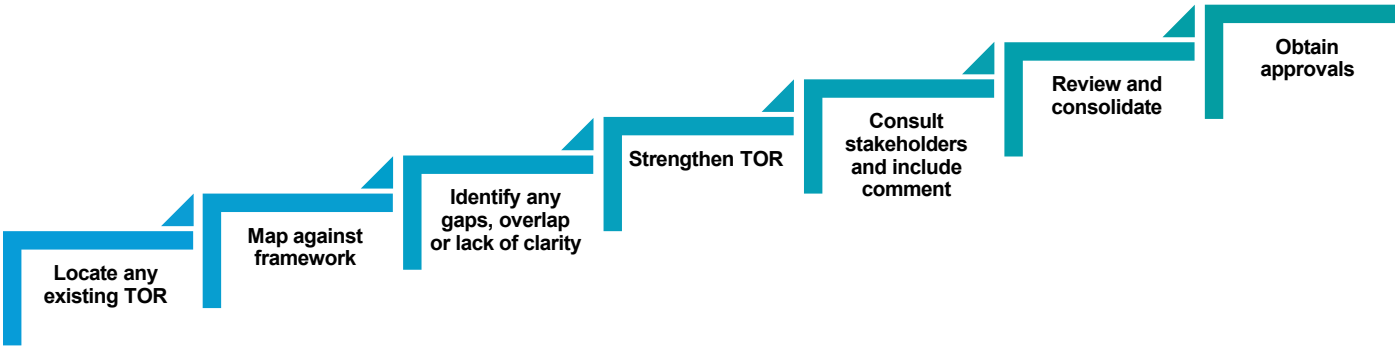

Figure 5: Process for development of TOR for DCS PTCs

Photo credit: William Vazquez

Results and Next Steps

The discussion of the TOR was an opportunity to educate staff on what PTCs are expected to do, how they should perform these duties, and the monitoring and reporting requirements to check that they are completing these tasks in accordance with required quality standards. The workshop provided an opportunity to discuss some of the issues and challenges unique to the supply of medicine in correctional settings. It also facilitated a common understanding of the roles, functions, and responsibilities of PTC members. The approach enabled participants to develop skills in drafting TOR for PTCs, which can be applied to other committees. Participants appreciated the simplicity and user-friendliness of the TOR guidance document. They commented that the framework headings and the guidance on the content to be included were helpful for drafting the TOR for each PTC. As a result of this activity, all six regions now have a TOR for the regional PTC, with key components being standardized and adaptions made to accommodate the individual context of each region.

Although it is too early to report whether PTCs have been revitalized or are meeting more frequently, it is anticipated that using this participatory approach in the creation of TOR will strengthen buy-in and contribute to the successful constitution and functioning of these important committees.

Lessons Learned

In all three cases, SIAPS staff and counterparts reported that the TOR guidance document was a useful tool for developing new TOR or revising existing ones. The guidance was used successfully in workshop settings by participants working in groups and also working directly with counterparts. Lessons learned from our experiences included that—

- Involving stakeholders in creating the TOR for a new governance structure or committee can be a first step to improve stakeholder buy-in, ownership, and commitment toward its subsequent functioning.
- Having a strategic vision and a clear purpose (which is included in the TOR) ensures that everyone has a clear understanding of the purpose of the structure, committee, task team, or forum and what it intends to achieve. Visioning exercises enable stakeholders to describe a future desired state by way of a picture as a step toward developing a common strategic vision.
- Aligning the TOR of interrelated committees is important to ensure that key functions of each committee are clearly defined; we found that once you start to review the TOR of one structure, it is not unusual to find that the TOR of other structures must be adjusted as well.
- In some cases, there may be a reluctance to include too much detail in the TOR of a committee because a lack of compliance with the TOR in the functioning of the committee could result in an audit finding; this is a situation that must be handled with sensitivity.

A committee should have a strategic vision that is shared by all members and understood by all stakeholders.

Crosscutting Lessons

In the experiences described above, some crosscutting lessons were learned. Key lessons were also learned about the importance of robust TOR to support good governance in the functioning of committees. These are summarized in the following table.

Component of the TOR	Lessons learned
Establishment and composition (What is the committee?)	• In the interest of transparency, the **name of the committee** must be carefully chosen to reflect the purpose and mandate of the committee. For example, in the case of the multi-stakeholder forum, the name chosen reflects the fact that the main focus is medicine availability rather than broader issues, e.g., medicine affordability. • It is important to check whether, as in the case of the committees involved in the contracting process, the committee is created in terms of an act or regulation and link the TOR carefully to the applicable **legislative mandate**, thus clarifying its mandate and preventing confusion about accountability and reporting.
Purpose (Why does it exist?)	• A committee should have a strategic vision that is shared by all members and understood by internal and external stakeholders. In the case of the multi-stakeholder forum, for example, a diverse group of stakeholders with different interests developed a **common vision** that was reflected in the TOR. • In cases where a sub-committee or task team is appointed, these bodies must also have a **clear purpose and defined tenure**. By making the work being undertaken by the group clear to internal and external stakeholders, transparency is enhanced and accountability improved. Holding unnecessary meetings with no clear purpose can also be prevented.
Membership (Who belongs?)	• A common challenge identified in the TOR reviewed was a lack of clarity in the way in which members of committees are nominated and appointed. The TOR must spell out clearly by whom and how potential members of the committee are **nominated**, by whom and how they are **appointed**, and who has the power to **terminate** membership. In addition it is also important that the TOR spells out clearly who is responsible for the appointment of the chairperson and the vice-chairperson. • When the number of stakeholders is large, the number of members must be kept to a **manageable size**. In the case of the multi-stakeholder forum, stakeholders from a similar group, such as pharmaceutical manufacturers, could make their own arrangements to nominate a representative of the whole group and organize a mechanism for providing feedback. • In some TOR, the **tenure of members** was not explicitly stated. In some instances, members are not appointed in their individual capacity but rather as representatives of an organization or institution. In these cases, the TOR must spell out clearly steps to be taken if the person ceases to occupy the relevant post in the organization/institution, and how and when he/she will be replaced. • Actions to be taken when a member is **unable to attend a meeting** should also be included. It is preferable to make provision in the TOR for a named alternate for a member rather than allow different people to replace members at meetings. The latter practice results in a lack of continuity leading to inefficiencies and potential difficulties around accountability of members if they are only involved from time to time.

Component of the TOR	Lessons learned
	• In some cases, the TOR may make allowance for **ex-officio members** who are not formally appointed as members of the committee but are consulted as needed. Such members may also belong to task teams or subcommittees. There are often individuals who are not available to attend all meetings but whose expertise is needed on occasion. Including these people as members of the committee may mean that the quorum may not be met. Members may also get "meeting fatigue" so care must be taken in choosing who becomes a core member and who can be a resource that is consulted from time to time. This approach supports the efficient use of resources. In cases where there are such members, the TOR must be explicit with regard to their position in the decision-making process. An example of this is the contracting committees, where experts in specialized areas such as diagnostics, are only needed when the tenders for such products are being considered.
Roles (Who does what?)	• A common challenge encountered was a lack of clarity regarding the **roles of the committee vis a vis the secretariat** with regard to functions such as minute-taking, which may affect the efficiency and effectiveness of the committee and cause conflict. Roles and responsibilities of various players must be clearly spelled out in the TOR.
Committee processes (How does it work?)	• The importance of stating the quorum in the TOR and adhering to this requirement cannot be overemphasized. During meetings, the chairperson must ensure that the **quorum requirements** are met to ensure that decisions taken are valid. • A common challenge that affects the committees is compilation of agendas and the preparation and the timely dispatch of documentation to members. Including clear time frames and assigning responsibilities for these functions in the TOR are important for the efficient functioning of committees.
Conduct of members (How do members behave?)	• To encourage trust in the committee and facilitate participation of stakeholders, clear provisions are needed to govern the **behavior of individual members** of a committee as well as the committee as a **collective**. For example, a common challenge was that although the TOR mentions that COIs must be declared, there was a lack of guidance on how to manage any COIs that arose.
Accountability (How does it report?)	• **Monitoring and evaluation** mechanisms with performance indicators to show whether the committee is achieving its purpose are often missing, so the committee has no idea how it is doing. As this is a common weakness, specific attention must be given to establishing and operationalizing a monitoring and evaluation framework for each committee to facilitate accountability.
Resourcing (How is it resourced?)	• The TOR often does not specify the details of how **committees will be resourced**. For example, who is responsible for providing the venue for meetings, payment for accommodation and travel, and providing refreshments during meetings.

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Conclusion

TOR are often viewed as a formality that must be prepared as a one-off exercise when establishing a new committee or body, rather than as a tool that supports its efficient functioning. Because the context in which committees operate may change over time, the TOR should be periodically reviewed to check if the goal and purpose of the committee are still relevant, whether the membership is appropriate, and, whether in the interests of efficiency, it is serving an important purpose. The TOR should also state who is responsible for initiating and undertaking this review. Also important is identifying key performance indicators to monitor the performance of the committee.

The guidance document developed by SIAPS proved to be very useful in helping country counterparts in South Africa review and revise the TOR of existing committees as well as develop TOR for new structures, such as a stakeholder forum. Having a structured template helped users identify gaps in existing TOR and enabled committee members to structure or reconfigure TOR in a logical manner. Although it is not possible at this stage to demonstrate that the improvements made to the TOR of the structures described in this brief improved their functioning, the processes that were used did raise stakeholder awareness of the importance of designing robust TOR. Follow-up and monitoring of some predefined key performance indicators is needed to evaluate whether having more robust TOR has a positive effect on the functioning of these committees.

Future work could include creation of a template to support the development of TOR for a group of committees with different functions that fall under the same organizational structure to facilitate alignment and prevent overlap of key functions and mandates. The TOR guidance document could also be used as a reference for the development of a tool to assess the functioning of a committee and adherence to good governance practices.

Committees that function inefficiently represent an enormous waste of time and resources, so it is of paramount importance that committees are constituted and continue to function in accordance with the principles of good governance to support effective decision making in the pharmaceutical sector. Well-functioning committees that make good decisions will benefit patients by supporting access to medicines and increasing confidence and trust in the system. Moreover, committees that include public representation provide an opportunity for citizens to provide input either directly or through groups that represent their interests.

Annex A. Guidelines for the Development of the Terms of Reference of a Committee

General Principles

1. Provide brief background on the committee.

2. State the basis for the establishment of the committee—for example, if the establishment of the committee is required or governed by legislation.

3. Include the broad purpose, aims, and objectives as well as the responsibilities of the committee.

4. If applicable, specify any legislation that gives the committee authority to act and/or should guide the work of the committee.

5. Use headings for each section. Examples of headings are provided in the table below.

6. Number the document using the 1, 1.1, 1.1.1 structure. This approach will help users navigate the document and make it easier to refer to different sections of the document.

7. Include only one principle/fact per numbered section.

8. Use language that is as clear and simple as possible.

9. Check that there are no ambiguities or inconsistencies in the document.

10. Include a list of definitions of terms that are used frequently in the document and may be understood differently by readers. Try to use standard definitions as far as possible. For example, if a concept is defined elsewhere—such as in legislation or other documents—use the standard definition.

11. Include a list of acronyms/abbreviations (and their definitions) used in the document.

The table below provides detailed guidance for writing the terms of reference of a committee. Note that the nature of the committee will determine which sections are applicable.

Content of Terms of Reference of a Committee

Heading	Content
Name of the Committee	• State the name of the committee. *Note:* *Name of the committee should give a clear indication of what the committee is about.*
Establishment of the Committee	• Indicate who establishes the committee. • State the date when the committee is to be/was established. *Note:* *Provide a clear description of why the committee was established and by whom.*

Heading	Content
Aims and Objectives of the Committee	• State the broad purpose/role of the committee. • Provide the reasons for the existence of the committee. *Note:* *Objectives of the committee should be well thought through, clearly expressed, and indicate what the committee is expected to accomplish.*
Composition of the Committee	• Specify the number of members who will serve on the committee.* • List role players/office bearers who should be members of the committee. • Indicate any stakeholders/constituencies who should be represented on the committee. • Describe competencies required for members to be eligible to serve on the committee, or that are required for the functioning of the committee.** *Note:* **Having too many members could make the committee ineffective. Having too few members can make it difficult for a committee to achieve a quorum.* *** Members of the committee should be individuals with the requisite knowledge, skills, and experience to ensure effective functioning of the committee and who are able to make a positive contribution to the work of the committee.*
Appointment of Committee Members	• State the criteria for appointing members. • Describe the process for nominating and appointing members of the committee.* • Describe how prospective members of the committee will be identified (nominated) and by whom.* • Describe how prospective members of the committee will be appointed and by whom.* *Note:* **It is important to differentiate between the nomination and appointment of members of a committee when these are two separate processes.*
Functions of the Committee	• State clearly the functions of the committee. • Outline the scope and limitations of the committee. • Describe the powers of the committee.
Accountability	• Indicate the person or entity to which the committee reports and is accountable. *Note:* *In some cases, members of a committee may have a responsibility to report back to their constituencies (include this information if applicable).*
Committee Portfolio Holders (e.g., Chairperson, Vice-Chairperson, Secretariat)	• Indicate which portfolios of the committee are needed to carry out various tasks on behalf of the committee—for example, those of chairperson, vice-chairperson, and secretariat.* • Describe the functions, powers, and responsibilities of each of the portfolio holders. • Outline the process of nominating and appointing portfolio holders—appointment may be by the committee itself or by an outside person or body. • Specify the period for which portfolio holders will serve. • Describe the— – Conditions under which the period of service of portfolio holders can be extended (if needed). – Process to be followed to extend the period of service of portfolio holders. – Conditions for dismissing portfolio holders (if needed) and the process to be followed. – Process for reassigning portfolios (if needed)—for example, in the absence of the chairperson. *Note:* **It is suggested that separate sections be included in the terms of reference to describe the various portfolios—for example, those of chairperson, vice-chairperson, secretariat, and others as needed.*

Heading	Content
Delegations to Committee Members or Portfolio Holders	• Describe any instances of delegation to members of the committee or portfolio holders. • Provide for delegation of powers on an ad hoc basis (if applicable). • Indicate that delegation of powers must be in writing.
Sub-Committees or Task Teams	• Indicate any sub-committees or task teams to be convened, if needed. • Describe who will approve the terms of reference of each sub-committee. • Describe how the activities of the committee and sub-committee/s will be coordinated. • Outline monitoring and evaluation activities in respect of each sub-committee's functional responsibilities.
Term of Membership	• Specify the period of office of members of the committee—for example, one or more financial years or calendar years. • Describe conditions for allowing extension of the period of office and the process to do this.
Termination of Membership	• Describe the conditions under which the membership of a member of the committee and/or sub-committee may be terminated. For example— – If the member is no longer available. – If he/she no longer holds the position by virtue of which he/she was appointed. – If he/she fails to attend a specified number of meetings with or without an apology (e.g., three consecutive meetings without an apology). – If an individual's behaviour is detrimental to the aims and objectives of the committee.* – Describe the process to be followed when terminating membership.** *Note:* **Such behaviors could include, for example, being found guilty of a criminal offense, or failure to comply with the conflict of interest policy.* ***This decision could be made by the committee itself or by the person who appointed a member.*
Holding Meetings	• Specify the number of meetings to be held each year. • Indicate how often meetings will be held. • Describe the process to be followed if more meetings are required. • Specify how much notice will be given to inform members about meetings. • Indicate where meetings will be held. • Indicate who is responsible for organizing meetings. • Describe the conditions under which non-members or visitors can attend a meeting of a committee. • Mention whether a member can nominate an alternative person to attend a meeting in his/her place.
Quorum	• Specify the number of members who must be present to allow a meeting to proceed (quorum).* • Describe the steps to be taken if a meeting becomes inquorate. *Note:* **It is standard practice for a quorum of a committee to consist of 50% of the membership plus one additional member.*

Heading	Content
Conducting Meetings	• Describe how agenda items will be generated. • List items that will be standing agenda items—for example, conflict of interest. • Describe how and when meeting agendas and other documents will be circulated/provided. • Describe how urgent matters will be handled between or in the absence of scheduled meetings. • Describe how meetings will be conducted by the chairperson. • Describe how decisions will be taken. • Describe how decisions will be documented.
Voting	• Indicate who is entitled to vote. • Specify how voting will be done—for example, show of hands, secret ballot. • Describe the process to be followed if there is no clear majority after voting—for example, the chairperson will have the casting vote and the procedure to be followed. • Specify any decisions that require the unanimous support of the committee.
Minutes	• Indicate who will provide the secretariat function for the meeting—for example, taking minutes. • Indicate when minutes are to be circulated/provided to members of the committee.
Code of Conduct	• Describe how committee members are expected to conduct themselves. • Explain the responsibility of members if they cannot attend a meeting. • Indicate how many meetings a member of the committee may miss before membership is terminated (see Termination of Membership above). • Specify that members must adhere to policies relating to conduct, confidentiality, and conflicts of interest.* *Note:* **It is recommended that committees have separate policies on confidentiality and conflicts of interest.*
Confidentiality and Conflicts of Interest	• Specify that every member must sign agreements relating to declaration of interest and confidentiality. • Describe how confidential materials and copyright issues will be identified and handled. • Describe the process for declaring and dealing with conflicts of interest. • If an online platform is used for sharing materials, describe how access will be managed and who will be responsible for posting the materials and maintaining the platform.
Reports, Recommendations, and Decisions	• Describe the format for reports and submissions to the committee—for example, submissions must be in writing. • Describe the format for the recommendations of the committee.* *Note:* **Recommendations/decisions of the committee must be based on facts and must be clear, accurate, and understandable in their content and purpose. Reasons for decisions must be documented.*
Reporting to Other Committees/Bodies	• Describe how the committee will interact/interface with or report to other committees/bodies.
Resources and Finances	• Indicate who will bear travelling and accommodation costs of committee members.
Evaluation and Review	• Describe how the performance of the committee will be assessed. • Indicate how often the terms of reference will be reviewed. • Indicate who approves the terms of reference of the committee.

References

1 Mid-year population estimates 2015 (StatsSA, July 2015).

2 South Africa. National Department of Health. Annual Performance Plan 2016/17-2018/19.

3 Cylus J., O. Wouters, and P. Kanavos. 2016. Understanding the role of governance in the pharmaceutical sector: from laboratory to patient. In Strengthening Health System Governance; Better Policies, Stronger Performance, edited by Greer S, L., M. Wismar, and J. Figueras. European Observatory on Health Systems and Policies Series. New York.

4 UNESCAP 2009. What is Good Governance? http://www.unescap.org/pdd/prs/ProjectActivities/Ongoing/gg/governance.asp [Accessed January 19, 2017].

5 Management Sciences for Health. Rice, James A., Shukla, Mahesh, Johnson Lassner, Karen et al. Leaders Who Govern. June 2015. Arlington, VA.

6 UNDP.1997. Governance for sustainable human development. http://www.pogar.org/publications/other/undp/governance/undppolicydoc97-e.pdf [Accessed January 19, 2017].

7 Medicines Transparency Alliance: A Review of the Pilot. 2010. http://www.medicinestransparency.org/fileadmin/uploads/Documents/MeTA_review_pilot.pdf [Accessed January 19, 2017].