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BUILDING CAPACITY IN SOUTH AFRICA FOR THE DEVELOPMENT OF PHARMACEUTICAL POLICIES, PROCEDURES, AND GUIDELINES



CHALLENGE **Readying a health system for universal health coverage**

As South Africa moves towards universal health coverage, improving good governance at all levels of the pharmaceutical system is critical. There is a need for robust policies and legislation; functional organizational structures such as Pharmaceutical and Therapeutic Committees (PTCs) at provincial, district, and facility levels; transparent evidence-

based decision making in key processes; and adequate oversight. Although the country has a strong legislative framework in place, variations in the structure and functioning of key committees (e.g. provincial PTCs) and a lack of clear criteria for making decisions throughout the pharmaceutical system remain as major challenges.

SIAPS ACTIVITIES **Policy documents guide improvements to pharmaceutical governance**

Only with a holistic, systems-level approach can policies, procedures, and other guidance documents provide the direction, integration, and coordination required to meet the unique pharmaceutical needs of a country. Working with in-country partners, SIAPS helps to analyze each unique country context, identify priority issues, harmonize approaches, and develop well-informed and locally appropriate policy documents to support good governance, which help to strengthen the performance of the pharmaceutical system. SIAPS also supports health ministries to engage stakeholders, including civil society, in a collaborative and transparent way through consultative workshops, solicitation of feedback, and information sharing.

In South Africa, SIAPS has collaborated with policy makers and stakeholders to develop several key policy documents to improve governance in the pharmaceutical system. These documents will help strengthen the manner in which decisions are made

and implemented in the selection, procurement, distribution, and use of medicines—ultimately contributing to improved access to and rational use of medicines. SIAPS collaborates with stakeholders and policy makers at national and provincial levels to develop these key documents using approaches that facilitate skills transfer to local partners.

Licensing of pharmaceutical facilities

South Africa's Pharmacy Act 53 of 1974 states that all pharmacies must be licensed by the National Department of Health (NDOH). Ownership of private community and hospital pharmacies was opened to non-pharmacist owners in 2003 but the criteria used to award licenses were weak and not available to applicants which resulted in multiple legal challenges. SIAPS and the NDOH, working in consultation with other stakeholders, developed revised criteria based on population per sub-district. The draft criteria aim to improve community access to pharmaceutical services by improving

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the distribution of pharmacies across districts and provide a clear basis for deciding when licenses should be issued. The *Proposed Criteria for Issuing of Pharmacy Licenses* in terms of the Pharmacy Act were published in the *Government Gazette* for public comment at the end of February 2014. SIAPS is working with a group of key stakeholders including NDOH, the Medicines Control Council, and the South African Pharmacy Council to produce a new draft based on comments received.

Standard Treatment Guidelines (STGs) and Essential Medicines List (EML)

SIAPS participated in the National Essential Medicines Committee to produce the revised *National Adult Hospital Standard Treatment Guidelines (STGs) and Essential Medicines List (EML)* and the *Tertiary and Quaternary Level Essential Medicine Recommendations*. Both documents are intended to support rational medicine use by providing guidance to prescribers in the choice of therapy. The hospital STGs and EML provide the list of medicines recommended for public sector hospitals and guidelines for their use, while the tertiary and quaternary guidelines serve a similar function for referral and specialized hospitals. Both documents were published in 2012. To make accessing this information more convenient, SIAPS made the hospital-level STGs and EML available through a smartphone application that was launched in January 2014 (available for download at: www.health.gov.za).

Pharmacoeconomic Guidelines

Support provided by the Strengthening Pharmaceutical Systems Program (SPS) and later SIAPS to the NDOH and Pricing Committee culminated in 2013 in the publication of *Guidelines for Pharmacoeconomic Submissions* published in terms of the General Regulations to the Medicines and Related Substances Act 101 of 1965. The guidelines provide a framework for assessing clinical and economic evidence to assist in choosing therapies based on comparative effectiveness.

Pharmaceutical and Therapeutics Committees

As South Africa moves toward universal health coverage, PTCs are needed at provincial, district, and facility levels to make decisions on medicines

availability and to support their rational use. In 2012, the SPS program compiled a technical report entitled “*Promoting the Rational Use of Medicines through Pharmaceutical and Therapeutics Committees in South Africa: Results, Challenges, and Way Forward*.” Disparities in the role and functioning of PTCs across the country was one of the challenges identified which prevented PTCs from fulfilling their mandate of promoting rational medicine use in the public health care system. To address this gap, the report recommended developing a framework for how PTCs should be established and function at all levels.

In response, SIAPS worked with the Gauteng Provincial PTC to produce *Guidelines for Implementation of Pharmaceutical and Therapeutics Committees in Gauteng Province*. The guidelines, launched in September 2013, support an integrated PTC network at provincial, district, and hospital levels; and set out the functions, roles, and structure of PTCs, as well as member responsibilities and accountability. Clear guidance is also provided on managing confidentiality and conflict of interest of members. The guidelines were used to re-establish the Gauteng Provincial PTC and to revise the terms of reference and guide the appointment of members for the KwaZulu-Natal Provincial. SIAPS also helped the Provincial Department of Health in Mpumalanga Province to prepare and publish the *Mpumalanga Medicines Formulary* which provides guidance to prescribers in the province on the availability and prescribing of medicines.

Service-level agreements between warehouses and facilities

Successfully managing arrangements to supply facilities with pharmaceuticals depends on developing robust agreements and establishing systems and indicators to monitor their implementation. In the Free State Province, SPS and later SIAPS facilitated a series of participatory stakeholder workshops to develop a service-level agreement between the pharmaceutical warehouse and health facilities. The agreement makes explicit the roles and responsibilities of the provincial head office, the provincial warehouse, facilities, and other parties involved in the procurement, storage, ordering, and receipt of medicines. The agreement was signed by the Free State Province Head of Health in August 2013. By providing clarity in the execution of processes, the agreement promotes transparency and accountability when procuring and distributing medicines. SIAPS has since assisted two more provinces to develop service-level agreements between the provincial warehouses and their clients.

| Health System Level | Document | Main purpose |
|---------------------|----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| National | <i>Proposed Criteria for Issuing of Pharmacy Licenses</i> | Sets new criteria for the licensing of pharmacies |
| | <i>National Adult Standard Treatment Guidelines and Essential Medicines List (revised)</i> | Provides guidance in the selection and use of medicine for patients receiving medical care at district and regional hospitals |
| | <i>Tertiary and Quaternary Level Essential Medicines Recommendations</i> | Provides guidance in the selection and use of medicine for patients receiving medical care at tertiary and quaternary hospitals |
| | <i>Guidelines for Pharmacoeconomic Submissions</i> | Provides a framework for selecting therapies based on clinical and economic factors |
| Provincial | <i>Gauteng Guidelines for Implementing Pharmaceutical and Therapeutics Committees (PTCs)</i> | Provides guidelines and tools for the establishment and functioning of PTCs at various levels |
| | <i>Mpumalanga Medicines Formulary</i> | Provide information on the medicines available for treatment of patients in Mpumalanga province |

NEXT STEPS Continuing to build capacity for good governance

The NDOH has identified the need to improve good governance by further strengthening the pharmaceutical services policy framework at national and provincial levels. In response, SIAPS will continue to work toward building capacity to develop key legislation, policies, procedures, guidelines, norms, and contractual documents. Next steps include the finalization of a national policy on PTCs and contractual and policy documents to support good governance in new

initiatives such as the Central Chronic Medicine Dispensing and Distribution program which is aimed at improving access to medicines by establishing partnerships between government and the private sector. SIAPS is also working with the NDOH to monitor implementation of new or revised policies, and has helped to introduce metrics and a dashboard at the national level to enable South Africa to monitor pharmaceutical service delivery across all nine provinces.

ABOUT SIAPS | The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program works to assure access to 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. For more information, visit www.SIAPSprogram.org.



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