SIAPS
TECHNICAL HIGHLIGHT

Strengthening the medicines regulatory system in Swaziland

CONTEXT

Swaziland is one of three remaining countries in the Southern Africa Development Community (SADC) Region that do not have adequate regulatory and legislative frameworks to control the use, importation, manufacturing, and exportation of medicines. This is in the face of increased incidence of counterfeit medicines in the region; up to 25% of marketed medicines are substandard, and this is up to 64% for antimalarial medicines,[1] according to a study conducted in 2011. Use of counterfeit and substandard medicines increases the burden of disease because of therapeutic failure, exacerbation of disease, and resistance to medicines. Swaziland's weakness in medicines regulation and limited regulatory enforcement is also exploited by those smuggling prohibited and counterfeit medicines into neighboring countries.

Regulation of medicines is weak because the current legislation governing the pharmaceutical sector and control of medicines (Pharmacy Act of 1929 and the Opium and Habit-Forming Drugs Act of 1922) does not provide for the establishment of a medicines regulatory authority (MRA), although both provide for a few of the functions that would ordinarily be those of an MRA. There is no quality control testing for medicines in the country, however, antiretrovirals (ARVs), antimalarial and anti-tuberculosis (anti-TB) medicines are quality assured through buying from World Health Organization (WHO) pre-qualified suppliers.

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1 World Health Organisation. 2011. Survey of the Quality of Selected Antimalarial Medicines Circulating in Six Countries of sub-Saharan Africa. Geneva, Switzerland: World Health Organisation; http:www.who.int/medicines/publications/WHO_QAMSA_report.pdf.

Medicines and medical supplies for public health care facilities are procured and distributed centrally by the Central Medical Store (CMS), established as a division under the directorate of health services in the Ministry of Health (MOH). The CMS is responsible for the procurement, storage, and distribution of essential medicines and supplies to government and faith-based organization-owned health facilities. There is no local pharmaceutical manufacturer at present. There are 5 major wholesalers and 60 community pharmacies registered with the Ministry of Commerce, Industry, and Trade. Imported medicines and those who import them are not registered, therefore, there is no information available to the MOH for decision making.

PROJECT APPROACH

It is against this background that the USAID-funded Systems for Improved Pharmaceuticals and Services (SIAPS) Program supported the MOH in its efforts to address the gaps in medicine regulation. One of the interventions was to prepare for the establishment of an MRA, the body that is responsible for all medicine regulatory activities. The Strengthening Pharmaceutical Systems (SPS)/SIAPS technical approach (figure 1) to strengthening pharmaceutical

governance was used to create an enabling environment that could evaluate governance gaps and develop and adopt comprehensive pharmaceutical policies, legislation, and regulatory processes. The technical assistance also aimed to support the development of a regulatory mechanism that could be supported by the appropriate technology and systems.

Source: Strengthening Pharmaceutical Systems. (2011). *Pharmaceuticals and the Public Interest: The Importance of Good Governance.* Management Sciences for Health: Arlington, VA, United States of America.

PROJECT IMPLEMENTATION

The MOH, with SIAPS and WHO-Afro Swaziland office support, conducted the following activities to establish the MRA:

i.   *Developed policies and legislation*
     SIAPS reviewed the national pharmaceutical policy and legislation to develop the Medicines and Related Substances Control Bill (MRSC; to establish the MRA) and Pharmacy Bill (to establish the pharmacy council). This was followed by an options analysis (with the
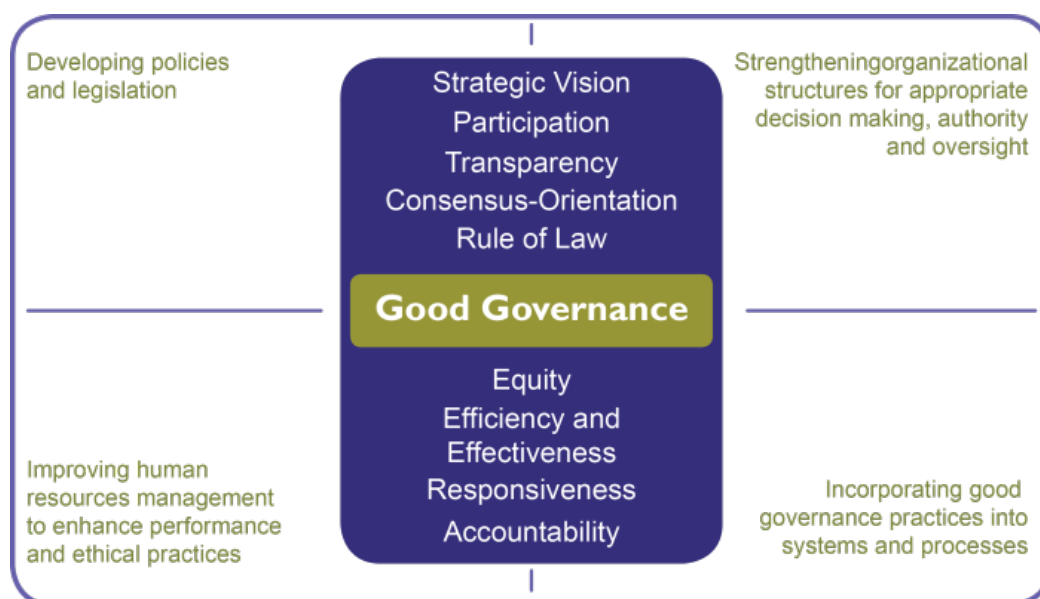
Figure 1. Strategies to support implementation of good governance principles in pharmaceutical services

assistance of a WHO consultant) for the MRA establishment. SIAPS further developed and costed the Pharmaceutical Strategic Plan 2012-2016 to provide strategic direction for MRA establishment activities and to guide development of a registration system, a pharmacovigilance system, and a national pharmaceutical quality control laboratory.

ii. *Strengthened organizational structures for appropriate decision making*
SIAPS supported the establishment of a five-member interim MRA working desk to perform some medicines regulatory functions and prepare for the establishment of the MRA upon enactment of the MRSC Bill.

iii. *Improved human resource management to enhance performance and ethical practices*
SIAPS built capacity of the members of the MRA desk through benchmarking consultative visits to more established SADC regulatory authorities.

RESULTS

The regulatory strengthening approach has resulted in MRSC no.7 of 2014 (which provides for establishment of the MRA) being approved by both Houses of Parliament in September 2015 and signed into law by the king in October 2016. This is now the MRSC Act, 9 of 2016. Draft regulations have been developed to facilitate implementation of the MRSC Act. An implementation plan is being used to guide the phased establishment of the MRA, the foundation of which will be the MRA working desk, which is currently under the Office of the Chief Pharmacist.

Importers of medicines were called to register with the MOH, and a medicines listing database has been developed through which the MOH monitors the registration status of medicines with other stringent MRAs. There are 6,749 medicines listed, 4,158 of which are registered with other MRAs; 2,591 have unknown registration status. The medicines listing does not constitute product registration, but is considered a preliminary step toward the future registration process. The medicine database enables the MOH to compile an audit of all medicines currently available in the market place. In addition, medicines available to the public are only those with known registration status; for ARVs and anti-TB medicines, only WHO pre-qualified medicines are approved for procurement. Medicine and therapeutic advertisements are now regulated by the MOH and donation guidelines are available to facilitate compassionate use programs.

WAY FORWARD

The MOH, with SIAPS support, has made considerable strides in the preparatory work for the immediate implementation and enforcement of the MRSC Act, now that it has been enacted. The MOH could still benefit from technical support in:

- Capacitating the MRA to perform its functions, once it has been established
- Finalizing and implementing the regulations for the MRSC Act
- Developing standard operating procedures and guidelines for the functioning of the MRA
- Conducting consensus-building workshops for stakeholders on the MRSC Act's regulations.