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# MODERNIZING LEGISLATION IN SWAZILAND TO IMPROVE THE CONTROL OF MEDICINES

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

## CHALLENGE Lengthy legislative processes impede improvements in pharmaceutical regulation

The weak regulatory system in Swaziland poses a threat to public health and safety and has been an obstacle in the country's effort to improve access to quality essential medicines and services for managing HIV, controlling tuberculosis, and delivering other priority public health interventions. The legislation governing the regulation of medicines, pharmaceutical establishments, and the pharmacy profession in Swaziland dates back to 1929 and no longer serves as an effective or relevant legal framework for the pharmaceutical sector. Specifically, the absence of a legal mandate for a national medicines regulatory authority has made it difficult for the government to assure the quality, safety, and efficacy of medicines used in the country.

For patients, this means that their health may be compromised if they cannot obtain the medicines they need or if they receive ineffective, inappropriate, or low-quality medicines that increase their risk for adverse reactions, drug resistance, and poor treatment outcomes. The availability of unregistered products in the market and the escalating numbers of unlicensed medicine vendors underscore the need for better regulation of the pharmaceutical sector as a whole.

The SIAPS predecessor program, Strengthening Pharmaceutical Systems (SPS), assisted the Ministry of Health (MOH) in developing two bills through an extensive stakeholder consultative process: the Medicines and Related Substances Control Bill and the Pharmacy Bill provide for the establishment of the first ever Medicines Regulatory Authority (MRA) and a Pharmacy Council to regulate the pharmaceutical sector. However, the enactment of these important bills has been held up since 2012 by lengthy legislative processes in the country, as well as by the competing responsibilities of the newly elected parliamentarians following the 2013 elections.


The Hon. Sibongile Ndlela-Simelane, Minister of Health, delivering her opening remarks to members of parliament.

# SIAPS ACTIVITIES

## Preparing for the implementation of new pharmaceutical legislation

Building on the work of SPS, SIAPS supported the MOH in Swaziland to present the bills for legal drafting and legislative approval, to resubmit them to the new Parliament and Cabinet following the 2013 election, and to advocate for their finalization and enactment. To build political will and expedite an otherwise lengthy parliamentary process, SIAPS assisted the MOH to conduct seminars and develop briefs to educate legislators on the importance of the new legislation and the content of the draft bills. Following stakeholder consultations, SIAPS helped revise the bills to gain additional political buy-in and local ownership.

To expedite the implementation of the Medicines and Related Substances Control Bill once passed, SIAPS also worked in partnership with the MOH to draft a set of accompanying regulations and develop an implementation plan for establishing the MRA. In addition, SIAPS helped the Chief Pharmacist's Office to develop guidelines and procedures for registering importers and created a database for cataloguing importers and the medicines they import.

# RESULTS

## Advancing a new legal framework

SIAPS assistance in strengthening governance and medicines regulation in Swaziland has contributed to the finalization of two bills—the Medicines and Related Substances Control Bill and the Pharmacy Bill—and the drafting of regulations that will be published to accompany the Medicines and Related Substances Control Bill once enacted. The revised bills have been approved by the Attorney General for presentation to the Cabinet. Following two SIAPS-supported seminars to 31 newly elected members of the House of Assembly and the Senate, the bills have been approved by the Office of the Attorney General and the new Cabinet for tabling before Parliament and then enactment into law.

The strategic plan for establishing the MRA has been approved by the MOH principal secretary. The MOH is now using the plan and the interim organizational structure proposed therein to establish new positions for the MRA and inform its staffing budget. In 2013, the MOH implemented the first step set out in the MRA plan for initiating the inspectorate function which called for partnering with the health inspectors and the police to conduct the first round of inspections. The MOH invited SIAPS to participate in a joint Royal Swaziland Police and Interpol operation to inspect establishments that function as de facto pharmacies in four regions and assess their compliance with good pharmacy practices and existing local laws.

Swaziland also has a newly developed database of importers of medicines, which contains information on five importers and over 6,000 products that they import. The MOH is now ready to implement the procedure for registering importers through the office of the Chief Pharmacist and plans to issue a certificate with the MOH seal to registered entities.

Through an inclusive and participatory process of legislation reform, SIAPS has helped lay the groundwork for improved regulation of the pharmaceutical sector in Swaziland. In addition to providing for the establishment of the MRA and the Pharmacy Council, the two bills have updated and clarified policies related to medicines registration, quality assurance, importation, and wholesale distribution of medicine. While legislative processes take time, through advocacy and technical support SIAPS has helped Swaziland to advance legislation that will facilitate access to safe, effective, and quality medicines for the people of Swaziland.

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# NEXT STEPS

## Fostering transparent and sustainable regulatory systems

In an effort to further increase efficiency, transparency, and accountability in the medicines registration process, SIAPS will support the implementation of Pharmadex, a web-based medicines registration software originally developed by the USAID-funded SPS program and now supported by SIAPS. Pharmadex is an integrated information system solution that facilitates management, documentation, dissemination, and sharing of regulatory information.

SIAPS will continue to support the MOH in advocating for enactment of the bills and, once approved, in supporting their implementation. SIAPS is also working to develop information, education, and communication materials on the proposed legislation for a wider scope of stakeholders, including the public, to ensure a widespread awareness of the bills and facilitate their introduction.

**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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