8 SIAPS-supported countries developed or updated and submitted 32 pharmaceutical laws and regulations for approval between 2011-2017

Sound legislation is critical to the establishment of an effective national regulatory framework and should be complemented by specific regulations. SIAPS provides technical assistance to country governments to advocate for, develop, and enact practical, enforceable legislation supported by the rule of law; develop sufficient regulatory capacity; and introduce and apply appropriate technologies.

By engaging a broad range of stakeholders—including ministries of health and finance, other relevant public-sector entities, civil society organizations, professional associations, and advocacy groups—SIAPS supports a participatory approach to the development of relevant pharmaceutical legislation.

<table>
<thead>
<tr>
<th>Country</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burundi</td>
<td>1</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>2</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>11</td>
</tr>
<tr>
<td>Guinea</td>
<td>2</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>1</td>
</tr>
<tr>
<td>South Sudan</td>
<td>2</td>
</tr>
<tr>
<td>Swaziland</td>
<td>2</td>
</tr>
<tr>
<td>Ukraine</td>
<td>11</td>
</tr>
</tbody>
</table>

For more information on SIAPS’ approach to strengthening pharmaceutical sector governance and the importance of laws and regulations, please visit: [http://siapsprogram.org/approach/pharmaceutical-systems/laws-and-regulations/](http://siapsprogram.org/approach/pharmaceutical-systems/laws-and-regulations/)
22 countries developed or updated guidelines, lists, and standard operating procedures with SIAPS support

A challenge that many low- and middle-income countries face is a lack of robust guidelines, lists, and SOPs that define norms and standards for performing pharmaceutical functions and are based on international guidance and best practices. Since the start of the project, SIAPS has assisted 22 countries to prepare or revise pharmaceutical and disease-specific guidelines and SOPs that reflect international guidance and best practices and provide the foundation for good governance and sound practices in pharmaceutical systems. 12 SIAPS-supported countries have updated national medicines, device, and equipment lists.

*Life of project figure (2011-2017)

For more information on SIAPS’ approach to strengthening pharmaceutical sector governance, standard treatment guidelines, and essential medicines lists, please visit: http://siapsprogram.org/approach/pharmaceutical-services/essential-medicines-lists/
Product registration improved in 10 SIAPS-supported countries through advocacy, process restructuring, capacity building, and the introduction or updating of information systems

Angola
Bangladesh
Benin
Mozambique
DRC
Ethiopia
Guinea
Namibia
Philippines
Swaziland

With support from SIAPS, three countries (Bangladesh, Mozambique, Namibia) have adopted the internationally-endorsed Common Technical Document format and specifications to standardize the medicines registration application process and the remaining seven have improved electronic information systems for product registration to make their processes more efficient and transparent. Of these, four countries (Bangladesh, Ethiopia, Mozambique, and Namibia) are implementing SIAPS’s web-based regulatory information system, Pharmadex.

*Life of project figure (2011-2017)

For more information on SIAPS’ approach to strengthening product registration and regulatory systems strengthening, please visit: http://siapsprogram.org/approach/pharmaceutical-systems/regulatory-affairs/
Preservice curriculum reform and development and in-service training are cost-effective and sustainable interventions that contribute to broader health system strengthening. They provide students and professionals with a critical foundation of knowledge and skills and allow them to continue to develop their competency to practice in the real world. Effective preservice training reduces the need for future large-scale and expensive in-service trainings. SIAPS worked with a number of university and government training programs to build the capacity of the pharmaceutical training institutions to enhance the pharmaceutical education capacity and produce pharmaceutical professionals locally as a key mechanism to sustain the system.

From October 2011 to September 2017, SIAPS assisted **4 countries** to develop or reform **11 preservice health professional training curricula** to address pharmaceutical topics.

From October 2011 to September 2017, SIAPS assisted **10 countries** to develop or reform **40 in-service health professional training curricula** to address pharmaceutical topics.

For more information on SIAPS and the role of pre- and in-service training in health system strengthening, please visit:  
[http://siapsprogram.org/2015/05/13/fighting-antimicrobial-resistance-with-pre-service-training/][1]  
3,022 people completed SIAPS-developed online learning courses in TB, governance, or antimicrobial resistance between 2011 and 2017

Developing stronger pharmaceutical systems that allow for greater and more equitable access to medicine hinges on the availability of skilled health care workers, program managers, and leaders—people with the appropriate and upgraded knowledge, skills, and competency-based training to effectively implement activities related to pharmaceutical management.

<table>
<thead>
<tr>
<th>Course</th>
<th>Number completing the course</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimicrobial Resistance (Part 1)</td>
<td>1,454</td>
</tr>
<tr>
<td>Antimicrobial Resistance (Part 2)</td>
<td>1,168</td>
</tr>
<tr>
<td>Good Governance in the Management of Medicines</td>
<td>363</td>
</tr>
<tr>
<td>QuanTB course</td>
<td>19</td>
</tr>
<tr>
<td>Using New TB Medicines and Regimens</td>
<td>18</td>
</tr>
</tbody>
</table>
Through December 2017, SIAPS trained 51,616 people in pharmaceutical management. Actual values presented below.

There are pervasive capacity gaps in the delivery of pharmaceutical services in resource-constrained countries. The lack of qualified pharmaceutical professionals and associates stems from institutions not being able to produce adequate numbers of personnel. SIAPS is working with in-country partners to building capacity to meet the demands of an advancing pharmaceutical system.

While it is difficult to avoid double counting entirely, the SIAPS data collecting and reporting system is set up to minimize it as much as possible.
From October 2011 to September 2017, SIAPS assisted in the development of 20 Global Fund proposals or grants that collectively amount to more than $500 million.

SIAPS continues to provide technical assistance to countries seeking additional financial support from the Global Fund. By developing Global Fund grant proposals and ensuring donor compliance to access additional rounds of existing funds, SIAPS countries have been able to access critical funding.
SIAPS contributed to more than $120 million in savings in 4 countries through improved pharmaceutical management practices, namely, improved national quantification and procurement, revised national essential medicines list, as well as revised hospital formularies and stock redistribution at service delivery points.

<table>
<thead>
<tr>
<th>Portfolio</th>
<th>Approx. Amount Saved (USD)</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>$6,380,000</td>
<td>SIAPS support for quantification support for tuberculosis; reproductive health/family planning; and maternal, newborn, and child health commodities</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>$186,678</td>
<td>Stock redistribution to reduce expiries</td>
</tr>
<tr>
<td>South Africa</td>
<td>$2,043,520</td>
<td>Revised formulary</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>$53,000,000</td>
<td>Pooled procurement</td>
</tr>
<tr>
<td></td>
<td>$62,000,000</td>
<td>Revised high-cost medicines list</td>
</tr>
</tbody>
</table>
More than $500 million—Value of Global Fund proposal and grant applications receiving technical assistance from SIAPS

<table>
<thead>
<tr>
<th>Portfolio</th>
<th>Approx. Value (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burundi</td>
<td>$65,847,948</td>
</tr>
<tr>
<td>Cameroon</td>
<td>$165,216,878</td>
</tr>
<tr>
<td>DR</td>
<td>$19,102,251</td>
</tr>
<tr>
<td>Guinea</td>
<td>$70,000,000</td>
</tr>
<tr>
<td>Namibia</td>
<td>$19,330,281</td>
</tr>
<tr>
<td>Niger</td>
<td>$39,184,958</td>
</tr>
<tr>
<td>Swaziland</td>
<td>$127,798,683</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$506,480,999</strong></td>
</tr>
</tbody>
</table>

SIAPS continues to provide technical assistance to countries seeking additional financial support from the Global Fund. By developing Global Fund grant proposals and ensuring donor compliance to access additional rounds of existing funds, SIAPS countries have been able to access critical funding.
Of those health facilities surveyed in 7 SIAPS countries, the proportion that used consumption data to inform ordering improved to **93%** over the life of the project.

Consumption data are the information on quantities of consumed pharmaceuticals or supplies during a reporting period. Consumption data offer the best estimates used to make decisions on quantities to supply and/or order.

Accurate information reduces wastage due to overestimation and stock-outs due to underestimation of commodity demand.

7 countries improved electronic information systems for medicines registration

Bangladesh*  
Benin  
Ethiopia*  
Mozambique*  
DRC  
Namibia*  
Philippines

* Pharmadex, a SIAPS-developed online medicines registration system, is used by Bangladesh, Ethiopia, Mozambique, and Namibia

43 countries use 7 electronic pharmaceutical management information systems developed by SIAPS

<table>
<thead>
<tr>
<th>SIAPS-supported tool</th>
<th>Where it’s used</th>
</tr>
</thead>
<tbody>
<tr>
<td>RxSolution</td>
<td>Lesotho, Namibia, South Africa, Swaziland, and Uganda</td>
</tr>
<tr>
<td>Pharmadex</td>
<td>Bangladesh, Ethiopia, Mozambique, and Namibia</td>
</tr>
<tr>
<td>QuanTB</td>
<td>Bangladesh, Brazil, Colombia, Dominican Republic, DRC, Ethiopia, Guatemala, Honduras, Mexico, Mozambique, Myanmar, Nicaragua, Nigeria, Philippines, Sierra Leone, South Sudan, Uruguay, Uzbekistan, Venezuela, Zambia, Zimbabwe</td>
</tr>
<tr>
<td>e-TB Manager</td>
<td>Armenia, Azerbaijan, Bangladesh, Brazil, Cambodia, Indonesia, Namibia, Nigeria, Ukraine, Vietnam</td>
</tr>
<tr>
<td>Quantimed</td>
<td>Afghanistan, Angola, Bangladesh, Cameroon, Ethiopia, Mali, Sierra Leone, South Sudan, and Swaziland</td>
</tr>
<tr>
<td>Electronic Dispensing Tool (EDT)</td>
<td>Ethiopia, Guyana, Haiti, Kenya, Namibia, Rwanda, Tanzania, and Zambia</td>
</tr>
<tr>
<td>Pharmacovigilance Monitoring System (PViMS)</td>
<td>Georgia, Philippines, and Swaziland</td>
</tr>
</tbody>
</table>

An effective health system depends on high-quality pharmaceutical information, from supply inventory records to financial data. SIAPS improves the quality and availability of information with a suite of electronic tools that help pharmaceutical managers develop sound policies and monitor supplies and services.
SIAPS worked with **29 countries** to strengthen supply chain components to improve the availability of essential medicines
73% of assessed health facilities across 10 countries now use a **standardized checklist** to monitor storage conditions, an increase from 16% in September 2014

![Graph showing comparison between Sept. 2014 and Sept. 2017](image)

Poor storage affects safety and quality; a disorganized store creates room for poor inventory control and increases the risk of expired and wasted products. As part of strengthening supply management functions, SIAPS supports improved storage conditions through standard operating procedures, lists and guides, and information management systems.

SIAPS supported 5 countries in ensuring safety of patients receiving new MDR-TB medicines

The first new TB medicines in more than 40 years—bedaquiline and delamanid—were endorsed by WHO for the treatment of MDR-TB and released onto the market in 2011 and 2012. However, uptake has been slow by countries for myriad reasons, including a lack of knowledge on how to manage implementation of new TB medicines.

To increase access to these new medicines, SIAPS built country capacity in Georgia, Kenya, Philippines, Swaziland, and Uganda to improve quantification, supply planning, and pharmacovigilance.

To learn more about how SIAPS supports the roll-out of new MDR-TB medicines, please visit: http://siapsprogram.org/2017/03/23/introducing-new-tb-medicines-in-five-countries/
5 national antimicrobial resistance strategies have been developed with SIAPS assistance

The irrational use of antimicrobials is common and accelerates the emergence of antimicrobial resistance (AMR). WHO recommends that countries develop national AMR strategies that align with WHO’s global action plan on AMR to ensure a coordinated response. SIAPS supports countries in building awareness of the threat of AMR, advocating for a coordinated response, and implementing interventions that support the goals of WHO’s Global Action Plan on AMR.

To learn more about SIAPS’ work on AMR, please visit: http://siapsprogram.org/wp-content/uploads/2017/11/USAID-SIAPS-Technical-Update-on-AMR.pdf
85% of the surveyed SIAPS-assisted sites in 6 countries have implemented pharmacovigilance or medicine safety activities.

<table>
<thead>
<tr>
<th></th>
<th>October 2013</th>
<th>Sept. 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>14%</td>
<td>85%</td>
</tr>
</tbody>
</table>

SIAPS works with in-country stakeholders to develop and implement pharmacovigilance and medicine safety activities that contribute to a reduction in medicine-related morbidity and mortality, protect patients, and improve treatment outcomes.

- **Pharmacovigilance activities** include spontaneous reporting systems for adverse events and suspected ADRs, active surveillance, risk management and communication, development of tools, trainings, and improving the use of data for implementing safety actions.
- **Medicine safety activities** include therapeutic effectiveness, rational use of medicines, and product quality. Medicine safety is a major component of pharmacovigilance.

Methodology and Data Validation

- Data are regularly collected for selected indicators at the country level from established LMIS systems, specific surveys, or information collected during site visits. SIAPS field offices enter this information into a database, which is reviewed at HQ to assess completeness, timeliness, and accuracy for each indicator. Once data are reviewed, and refined if necessary, they are published in quarterly dashboards, and used by SIAPS staff for reporting and decision making.