PHARMADEX LAUNCHED IN BANGLADESH

On May 17, 2017, the Honorable Minister Mohammad Nasim, Member of Parliament (MP), Ministry of Health and Family Welfare (MOHFW), officially launched Pharmadex in Bangladesh. Pharmadex (http://pharmadexbd.org/) is a web-based integrated information system that facilitates the submission, review, and evaluation of medicine registration applications and dossiers on the basis of international standards and formats. Minister Mohammed Nasim appreciated the initiative taken by the Directorate General of Drug Administration (DGDA) to digitalize its regulatory systems and congratulated USAID and SIAPS for their system strengthening work with DGDA.

Honorable MOHFW Minister Mohammad Nasim (center-right in the black vest) attended the launch event as chief guest. Photo credit: A. R. M. Kamal, MSH Bangladesh

The USAID-funded SIAPS Program, implemented by Management Sciences for Health (MSH), partnered with the DGDA to improve the efficiency of the country’s medicine registration process. DGDA, with SIAPS technical assistance, adapted Pharmadex to meet the context of Bangladesh to move toward a more efficient and transparent medicine registration system from the current paper-based process. SIAPS facilitated trainings for DGDA officials and selected pharmaceutical industry representatives to build their capacity to use this tool successfully. SIAPS also
supported DGDA in adopting Common Technical Document (CTD) guidelines to make sure that the dossiers submitted to DGDA meet international standards. At the event, a technical presentation on the system was made by SIAPS Technical Advisor Dr. Afsana Alamgir Khan.

A total of 150 participants attended the launch ceremony, including senior officials from the MOHFW, DGDA, and Directorate General of Health Services (DGHS) and representatives of the Bangladesh Association of Pharmaceutical Industries (BAPI), the Bangladesh Chemist and Druggist Samity (Association), pharmaceutical manufacturers, USAID, and other international and national organizations, academia, and media. After the event, SIAPS worked with DGDA to develop an action plan for Pharmadex implementation, and training plans for DGDA staff and pharmaceutical companies have been planned accordingly. DGDA already circulated official letters to 10 companies instructing them to submit registration by using Pharmadex.

**SIAPS Coorganizes D4D in Health Conference in Dhaka**

The SIAPS Program coorganized the International Conference on Data for Decision (D4D) in Health, held successfully April 1-3, 2017, in Dhaka, Bangladesh. This conference was a follow-up event of the 2016 regional conference on Measurement and Accountability for Health. The D4D in Health conference was set to highlight the global and regional progress to date in strengthening the health management information system to showcase innovations from institutes, academics, and development partners across the world and to present the country’s status on ensuring access to information, data visualization, and the accountability and management of the system.

The first two days of the event were a high-profile seminar bringing together more than 200 representatives of 19 countries, including the United States, Norway, Haiti, Myanmar, and Sri Lanka. The third day focused on a field visit around Dhaka and neighboring districts to see different health information systems currently in use at different facilities under DGHS.

At the conference, Zahedul Islam, Country Project Director of SIAPS Bangladesh, cochaired a session under “Theme 2: Making Measurement Easier – Data Visualization”. Mohammad Golam Kibria, Senior Technical Advisor (Health Information System [HIS]) presented on “Creating a culture for data use: It takes a system strengthening approach” and also led one skill-building session on “Visual Analytics using Excel”. An exhibition booth was put on by SIAPS at the conference to feature different HIS tools supported by the program and to showcase country-specific results.

SIAPS team with Professor Dr. Abul Kalam Azad (center), Director General (DG) of Health Services during the D4D in Health event.
As a pharmacist, Md. Jahidul Hasan has worked in several hospitals, but it was not until he joined Square Hospital Limited (SHL) that he learned about pharmacovigilance (PV). SHL is a 400-bed tertiary-care private hospital in Dhaka, Bangladesh, that serves an average of 1,200 outpatients each day.

“I joined SHL in 2013 and learned what PV was all about when our hospital became a part of DGDA’s PV program,” Jahidul says.

The DGDA, with technical assistance from the US Agency for International Development-funded SIAPS Program, officially launched Bangladesh’s national PV program in 2013. The DGDA first introduced the PV program at 20 private and public hospitals, including SHL, and 13 pharmaceutical companies. Since then, the DGDA and SIAPS have organized trainings for PV focal persons in these hospitals and pharmaceutical companies to build their skills and knowledge on PV and increase adverse drug event (ADE) reporting.

After participating in one such training in 2014, Jahidul, who serves as SHL’s PV focal person, shared his new knowledge with the hospital’s Pharmacy and Therapeutics Committee (PTC) to show how SHL can incorporate PV into its regular activities. The PTC is responsible for overseeing the clinical activities of SHL. Although the committee monitors ADEs among inpatients, it did not have a clear reporting structure until 2013.

According to Jahidul, “At first things were slow, but gradually the wheel started to move and PV took a stronger shape in SHL. We developed our own reporting flow for ADEs. Every doctor and nurse, at the time of joining [the hospital], is given orientation about PV. We also keep emergency contact numbers and name of the PV focal person hanging on the notice boards of each ward so duty nurses can promptly report if any ADE occurs.” He adds proudly, “Every event must be reported—this is how PTC focuses on PV now.”

Currently, 30 hospitals and 30 pharmaceutical companies with designated PV focal points are working as “sentinel surveillance sites” to implement PV interventions under the DGDA. To strengthen the ADE reporting system, SIAPS also helped the DGDA develop PV guidelines and tools and form an Adverse Drug Reaction Advisory Committee (ADRAC) to evaluate, analyze, and make recommendations on ADEs. A team comprising DGDA officials and SIAPS technical advisors makes regular monitoring visits to implementing facilities to follow up on PV activities. As of April 2017, the DGDA had received more than 1,300 ADE reports. Of these, 393 complete reports were reviewed by ADRAC and uploaded to the World Health Organization’s (WHO) VigiFlow database.

According to the DGDA, SHL is one of the facilities that regularly submit ADE reports. For its commitment to ensuring medicine safety, SHL stands as a model for other private and public hospitals in the country.
18th LCF Meeting Held

The 18th Logistics Coordination Forum (LCF) meeting was held on February 6, 2017, with the participation of key government entities and donor representatives. The meeting was chaired by Sheikh Md. Shamim Iqbal, DG, Directorate General of Family Planning (DGFP) and chairperson of LCF. The LCF is usually held twice a year to accelerate supply chain-related activities and strengthen overall supply chain management and procurement of DGFP by improving coordination among different stakeholders.

At this meeting, it was decided that a procurement plan would be prepared and a selection process for a preshipment inspection firm will be conducted with technical assistance from SIAPS. Also, the decision was made that the procurement process for government funding will be initiated, and a contract will be signed if funds become available. The forum decided that actions will be taken to avoid implant stock-outs, and the DGFP will write a letter to the deputy directors of each district to accelerate the condemnation process. The forum also discussed how DGFP will try to introduce second-generation contraceptive items within the next two years.

SIAPS Assists DGFP to Cope with Post-Fire Supply Management Challenges

As one of DGFP’s major partners, SIAPS has been closely working with DGFP to handle the supply-related challenges that occurred after the devastating fire at the central warehouse on April 9, 2017. The fire destroyed most of the family planning commodities, including maternal and child health commodities, and IT equipment. At DGFP’s request, embedded SIAPS technical advisors, led by Senior Technical Advisor (Logistics) Md. Abdullah, worked with the DGFP to retrieve information from the Warehouse Inventory Management System/electronic Logistics Management Information System to prepare an inventory of medicines and commodities that were in the warehouse at the time of the fire. SIAPS also assisted with the physical inventory (count) of remaining items. The difference in these two inventories is the items that were lost; the information also made it possible to forecast a stock-out of commodities. Based on the initial assessment, SIAPS immediately recommended an emergency procurement of injectables and IUDs; SIAPS technical advisors at DGFP will assist with procurement package submission.

DGFP formed a supply chain monitoring committee to ensure rational distribution of contraceptives and medicines. SIAPS has also prepared an advance supply plan for contraceptives that donors committed to giving DGFP in case of emergency. SIAPS will continue to technically assist DGFP for the remaining life of the project to stabilize the family planning stock situation in the country.

DGDA’s GMP Inspection Capacity Strengthened

To strengthen DGDA’s Good Manufacturing Practices (GMP) inspection processes, SIAPS set up a six-day training for DGDA’s 15 Dhaka-based senior officials in April 2017. A SIAPS consultant facilitated the training that included classroom practical exercise and mock inspection. Through this training, participants learned about advanced GMP, especially inspection techniques, change control, deviation management, the quality management system, GMP aspects in plant design, process

GMP training participants during a mock inspection visit.
validation, the role of inspectors, and the inspection preparation checklist. As part of the training, DGDA inspectors visited three pharmaceutical companies in three groups to walk through the steps of inspecting manufacturing facilities using newly learned GMP inspection tools and submitting inspection reports afterwards. Both DGDA and pharmaceutical companies appreciated the training and emphasized that such engaging and advanced GMP training should be given to DGDA regularly.

**SIAPS Develops Interoperability Between DHIS2 and e-TB Manager**

Recently, SIAPS successfully developed interoperability between the District Health Information System 2 (DHIS2) and e-TB Manager, which makes tuberculosis (TB) patient summary data available on DHIS2 for indicator reporting and decision making. DHIS2 is an open source platform that collects and stores monthly aggregated summary data from a wide range of health systems across the nation and generates reports; on the other hand, e-TB Manager is a web-based, patient management tool that captures data across all aspects of TB control and management.

DGHS introduced DHIS2 as the national HIS platform in 2012, whereas the National TB Control Program (NTP) has been using e-TB Manager since 2010, which now runs at 218 subdistricts, including all multidrug-resistant sites. To develop the interoperability, SIAPS collaborated with HISP Bangladesh and undertook a master-facility and data-structure mapping for these systems. After a deep dive into both tools, these were appropriately linked and interoperability was developed through the standard web application programming interface using hypertext transfer protocol that followed a standard integrated health information architectural framework. Using the interoperability function, NTP will be able to push the summary data from e-TB Manager to DHIS2 and can generate WHO-approved quarterly reports related to TB case finding and treatment results.

**Basic Logistics Management Capacity of DGHS Officials Enhanced**

To strengthen DGHS' logistics management systems, SIAPS has helped develop standard, uniform, manual inventory management tools (stock register, issue voucher, indent and issue vouchers, bin card, etc.). With SIAPS technical assistance, DGHS is rolling out these tools in different phases to the different levels of stores under the directorate across the country.

As part of the process, SIAPS has been also conducting two-day basic logistics management trainings for DGHS staff to build their capacity in basic logistics management. The third episode of this training was conducted during January to March 2017 for 412 health officials from 11 districts (covering 105 subdistricts), bringing the number of districts that are using standard inventory tools to 34. For many of the participants, this was the first training of its kind and they were very enthusiastic about it. The storekeeper of the district reserve store at Madaripur commented, “This is the best training I received in my life.” DGHS officials also attended the training to motivate local-level health managers. At Madaripur district, the civil surgeon was present at the opening of the training and remarked, “Thank you SIAPS for organizing this two-day training course for the storekeepers. Such type of training should have been organized by the Government earlier for proper management of stores.”
SIAPS Officially Hands Over SCMP to MOHFW

On March 4, 2017, SIAPS successfully completed the entire transfer and installation process of the Supply Chain Management Portal (SCMP; https://scmpbd.org/), the online central repository for all procurement and supply chain activities under the MOHFW. The SIAPS IT team worked with the DGHS Management Information System team to facilitate the technical hand over process and critically observed the overall performance of the portal until April 12, 2017, for any technical issues. As the portal transition was completed with satisfactory results, the SIAPS country project director officially informed the DG of DGHS about the accomplishment. Earlier in 2016, SIAPS had submitted portal-related technical documents to the MOHFW. This final transition marked the successful implementation of the advocacy and policy plan that SIAPS and MOHFW jointly developed in 2014 to ensure the tool’s sustainability; the process can be an example of country ownership for other partners. Going forward, SIAPS will hold technical sessions on the management and maintenance of the SCMP with key MOHFW officials in August 2017.

DGFP Officials’ Technical Capacity to Develop Quality Tender Documents Enhanced

Annually, DGFP prepares approximately 40 to 50 procurement packages for medicines and other goods using World Bank and Government of Bangladesh funds following the guidelines, rules, and acts of these two authorities. It has been observed that, for similar types of items, different procurement desks in DGFP use different sets of conditions when preparing tender documents; confusion is created because the terms and conditions should be similar. Therefore, SIAPS facilitated a one-day workshop on the importance of uniform tender documents on January 17, 2017, for the officials of the logistics and supply unit of DGFP. At the workshop, Muhammad Jasim Uddin Bhuiyan, Assistant Director (Local Procurement) and Shahadat Hossain, Procurement Officer of DGFP made presentations on conceptual harmonization when preparing tender documents, especially the qualification criteria and schedule of requirements for procurement of health sector goods and goods other than medicines. SIAPS Team Lead (Procurement and Logistics) Dr. Abu Zahid also led a discussion on the common mistakes made during the preparation of tender documents. The event really helped enhance participants’ technical capacity to ensure quality and harmonized tender documents for all possible procurements to be carried out under the new sector-wide program.

Dissemination of DGDA’s Five-Year Strategic Plan in Bangladesh

After a year-long process, on June 8, 2017, SIAPS successfully disseminated DGDA’s five-year strategic plan (2017-2021) in the presence of officials from MOHFW, USAID, the US Pharmacopeial Convention’s Promoting the Quality of Medicines (USP-PQM) Program, WHO, executive members of BAPI, representatives of pharmaceutical companies, and all directors of DGDA. In March 2016, WHO engaged with various stakeholders (SIAPS, USAID, the Bill & Melinda Gates Foundation, USP-PQM, the International Vaccine Institute, and the World Bank) to develop a road map and strategy to coordinate efforts to strengthen the country’s regulatory systems.

One of the defined key activities was the development of a five-year strategic plan aimed “at strengthening medicine regulatory systems in Bangladesh by addressing the weaknesses and threats following seven strategic goals.” These goals include ensuring an appropriate legal and institutional framework, mobilizing adequate financial resources, and ensuring operation of a functional quality control laboratory.
The strategic plan was greeted positively by participants. Managing directors of Popular Pharmaceuticals and Incepta Pharmaceuticals indicated that “the timely initiative DGDA took is commendable,” adding that they wish to see DGDA among the strongest regulatory authorities in the country. The DG of DGDA appreciated SIAPS’ commitment to DGDA’s activities and wishes for a completion of the strategic plan within the time period.

Major General Mohammad Mustafizur Rahman (fifth from the right), DG of DGDA attended the event as chief guest.