

# SIAPS BANGLADESH

Quarterly Newsletter

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## ONLINE MEDICINE REGISTRATION SYSTEM IMPROVES PHARMACEUTICAL MANAGEMENT

SIAPS Bangladesh is assisting the Directorate General of Drug Administration (DGDA) to introduce Pharmadex, an online medicine registration management system. As a first step, SIAPS supported the establishment of a taskforce, composed of six DGDA officials. The taskforce is responsible for developing an implementation plan to launch Pharmadex and for the adoption of the Common Technical Document by the Directorate. SIAPS organized practical training sessions on Pharmadex to orient the taskforce to the medicine registration application process and the functionalities of Pharmadex. It also obtained feedback on potential areas for improving the system. The training sessions resulted in the development of a Bangladesh-specific medicine registration application template and a description of the work flow process for Pharmadex. To provide hands-on demonstration and testing of Pharmadex for all DGDA officials, a two-day user acceptance testing (UAT) workshop was held on August 19-20, 2014. The workshop oriented participants to the application process and functionalities of Pharmadex and obtained feedback on potential refinements to the system. Next steps include continued piloting of Pharmadex at the DGDA and technical assistance to the Directorate to conduct UAT for stakeholders, namely, pharmaceutical industry representatives who are the applicants for medicine registration.

## FORECASTING EXERCISE YIELDS USD 4.1 MILLION IN SAVINGS FOR THE DGFP

The third Forecasting Working Group (FWG) meeting of the Directorate General of Family Planning (DGFP) was held on August 11, 2014. Technical assistance was provided by SIAPS. Chaired by the DGFP Director General, Md. Nur Hossain Talukder, the objective of this meeting was to present the annual needs for reproductive, maternal, neonatal, and child health (RMNCH) commodities for fiscal year (FY) 2014-15 and to prepare the procurement plan. The FWG was established in the DGFP with technical support from SIAPS. Its purpose is to forecast RMNCH commodity needs and ensure that resources are allocated to meet those needs. The DGFP has a five-year (2012-2016) forecast and a two-year supply plan for family planning (FP) commodities. Although the DGFP had initially planned



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to procure 460,000 implants for FY 2014-15, after a systematic forecasting exercise was completed with assistance from SIAPS, the need for implants was determined to be much less. At the FWG meeting, the DGFP decided to purchase 410,000 implants for FY 2014-15, realizing a savings of about USD 4.1 million.

### **SDP DASHBOARD MODULE FACILITATES EVIDENCE-BASED DECISION MAKING**

In 2014, with assistance from SIAPS, the DGFP introduced the service delivery point (SDP) dashboard module. The module is an enhancement to the DGFP's Supply Chain Information Portal (SCIP) and operates on the Upazila Inventory Management System software platform used at the upazila (sub-district) level. Its purpose is to track the stock status of contraceptives at SDPs (i.e., family welfare assistants, health and family welfare centers, nongovernmental organization clinics, maternal and child welfare centers). The module facilitates effective and efficient commodity management by ensuring the availability of contraceptives, including condoms, oral pills, IUDs, injectables, and implants and by preventing stock-outs at the last mile. The SDP dashboard module was piloted from March to September 2014 in 20 upazilas in four districts throughout Bangladesh. To introduce the module, 1,692 participants (72% female), including upazila-level DGFP staff and SDP personnel, in the 20 upazilas were given a day-long orientation.

After the successful completion of the pilot phase, a dissemination workshop was held on September 22, 2014, with assistance from SIAPS. Its purpose was to share results of the pilot test with the DGFP Director General, Md. Nur Hossain Talukder, and line directors. A presentation was made highlighting how the SDP dashboard module reduced the stock-out rate for contraceptives at the SDP level from 4.08% in February 2014 to 0.96% in August 2014, a decrease of 3.12 percentage points. Senior-level officials were also informed about how the module facilitates decision making by the DGFP through the use of real-time data. With the availability of key information in the module (for example, the phone numbers and locations of SDPs), supervision and monitoring at the field level are enhanced. During the dissemination workshop, the DGFP director general

called an upazila FP officer and a family welfare assistant to check on a stock status issue identified when reviewing the data in the SDP dashboard module. The module has strengthened awareness among SDP-level staff about the importance of accuracy in reporting and better performing their duties to avoid stock-outs. At the conclusion of the workshop, officials of the DGFP and the US Agency for International Development (USAID) decided to roll-out the SDP dashboard module to all 488 upazilas, with technical support from SIAPS.

### **DGFP WAREHOUSE MANAGEMENT SYSTEM STRENGTHENED**

Poor warehouse management leads to the waste of financial resources and shortages of essential health commodities, ultimately decreasing the quality of public healthcare. SIAPS continues to assist the DGFP to improve its warehouse management practices. For example, SIAPS recommended that DGFP officials at the central and regional levels issue notifications to condemn un-serviceable and obsolete items from their warehouses. Subsequently, the DGFP conducted a condemnation process involving nearly 254 upazila FP stores, the central store, and three regional warehouses. This entailed the disposal of un-serviceable and obsolete items that were limiting storage space for usable reproductive health (RH) and FP products. As a result of this initiative, about 16,000 square feet of storage space is now available to store usable products, thereby enhancing product safety and maintaining product quality.

### **DGDA PHARMACOVIGILANCE CAPACITY ENHANCED**

SIAPS continues to increase awareness of pharmacovigilance in Bangladesh. It provided support for three members of the Adverse Drug Reaction Monitoring (ADRM) Cell of the DGDA to attend an international training program offered by the International Society of Pharmacovigilance and the Uppsala Monitoring Centre, June 5-7, 2014, in Manila (Makati), Philippines. As a result of this training, the ADRM officials better understand the significance of harmonization and adherence to international standards for pharmacovigilance reporting systems; learned about the need to obtain structured, high-quality data for individual case safety reports; and gained knowledge on the use of appropriate tools to improve detection, monitoring, reporting, and prevention

of adverse events in Bangladesh. The training also familiarized them with communication and dissemination strategies for pharmacovigilance information with the public and other stakeholders.

### TRAINING ON GMP INSPECTIONS INCREASES DGDA REGULATORY CAPACITY

To strengthen the capacity of the DGDA to undertake Good Manufacturing Practice (GMP) inspections and to properly adopt the GMP guidelines in accordance with World Health Organization (WHO) standards, SIAPS facilitated a training program for DGDA officials in May 2014. The training featured mock inspections, site visits, and debriefings, and a formal training session.

On May 25-26, 2014, a mock inspection was conducted by two groups of four DGDA inspectors at two pharmaceutical companies (Eskayef and Renata Pharmaceuticals Ltd.). The inspection was observed by the trainer. As part of the mock inspection, site visits took place that helped assess the DGDA's existing GMP practices and identify

gaps in its inspection procedures. Concerns identified and corrective actions were presented to 18 DGDA officials during a debriefing held on May 27, 2014. Then, a two-day basic training on GMP inspections was conducted for 75 DGDA officials on May 28-29, 2014. The training focused on coaching the officials to better understand issues that are vital to a successful GMP inspection; maximizing inspection efficiency; and recognizing fraud, counterfeiting, and otherwise illegal practices during an inspection. DGDA officials increased their knowledge about how the manufacture of poor-quality medicines, due to non-compliance with GMP, can negatively affect the nation's health.

Next steps to increase the regulatory capacity of the DGDA include additional site visits (coached) to conduct GMP inspections for the 75 DGDA inspectors; advanced training on GMP for DGDA officials, both in-country and outside of Bangladesh; and updating the quality management system manual to an agency-level ISO 9001-type version.

### BANGLADESH BECOMES THE 300TH MEMBER OF THE RHSC

The DGFP in Bangladesh has become the 300th member of the Reproductive Health Supplies Coalition (RHSC). A "Declaration of Intent" was signed by Mr. Md. Nur Hossain Talukder, Director General, DGFP, on August 3, 2014. SIAPS carried out a series of advocacy activities with the Ministry of Health and Family Welfare (MOHFW) to facilitate clearance to become a member.

The Declaration of Intent states, in part: "By means of this declaration, the Reproductive Health Supplies Coalition and DGFP express their intentions to work together as partners in the international effort to ensure that all people in low- and middle-income countries are able to access and use affordable, high-quality reproductive health supplies. The Coalition recognizes the DGFP as an official member of the Reproductive Health Supplies Coalition, with all the rights and privileges that entails. The Coalition agrees

to provide the DGFP with full access to all its tools, resources, and information. It also agrees to assist the DGFP in networking with other Coalition members and affiliates. The DGFP may join and participate in any of the Coalition's Technical Working Groups, and may vote for and serve as the Head of any Working Group in which they are involved. The DGFP is also eligible, if elected, to serve as a member of the Executive Committee, including the role of Chair. For its part, the DGFP accepts the Coalition's vision to ensure that all people can access and use affordable, high-quality supplies to ensure their better reproductive health. The DGFP accepts the Coalition's strategic goals and core values of equitable access to supplies, broad product choice, gender equity and country ownership of the development process. Finally, the DGFP agrees to participate actively in the work of the Coalition and allow its name to be listed publicly as a Coalition member."

### **HEALTH MANAGER'S CAPACITY STRENGTHENED TO MINIMIZE GAPS IN PROCUREMENT**

SIAPS provided technical support to the Procurement and Logistics Management Cell (PLMC) of the MOHFW to organize 14 workshops on the Framework Agreement for Procurement of Frequently Used Health, Population and Nutrition Sector Goods and Related Services in seven divisional cities of Bangladesh, during the period September 3–October 1, 2014. The workshops were held subsequent to the issuance of a government order by the MOHFW that allows for streamlined processes through multi-year procurements and multiple deliveries. The main goal of the workshops was to increase participants' understanding of the preparation of standard tender documents based on the framework agreement, which is a special kind of long-term agreement between the lead procurement entity and sole or several supplier(s). A total of 512 participants attended the workshops, including district civil surgeons, deputy district civil surgeons, deputy directors (health) at the division levels, and upazila health and FP officers.

Major recommendations made by participants during the workshops were that:

- Participants be responsible for expanding the roll-out of the framework agreement implementation process
- Workshops on the framework agreement should be arranged for officers from the Directorate General of Health Services (DGHS) and the Central Medical Stores Depot (CMSD), which are involved in procurement at the central level and related policy issues

### **US AMBASSADOR MOZENA PRAISES ACHIEVEMENTS IN PREVENTING STOCK-OUTS OF FP PRODUCTS**

On September 30, 2014, the US Ambassador to Bangladesh, His Excellency Dan W. Mozena, visited the DGFP regional warehouse in Chittagong, at which SIAPS has supported the use of the SCIP. A briefing session was organized by the DGFP, which included Mr. K. M. Shafiul Alam, Divisional Director, Family Planning, Chittagong Division; Dr. Sheikh Rukunuddin Ahmed, Deputy Director, Family Planning, Chittagong District; the ambassador and other officials from the US Embassy; SIAPS staff; Chittagong regional warehouse staff; and journalists. The ambassador was oriented on how SCIP

functions and helps the DGFP prevent stock-outs. Presentations were made on DGFP supply chain management and the SCIP by Mr. Mohammad Shah Alam, Regional Supply Officer, Chittagong Warehouse, and Mr. Mohammed Abul Kalam, Assistant Director, Port Clearance, respectively. During his speech, the ambassador praised Bangladesh's efforts in avoiding stock-outs of FP products over the last four years. He said, "Amazing things are happening in Bangladesh. The country is on a trajectory to achieve the Millennium Development Goals to slash maternal mortality and under-5 child mortality rates." He added that the fertility rate in Bangladesh has gone down from 6.3 live births per woman in 1971 to 2.2. He commented that such a reduction in the fertility rate would not be possible if there were stock-outs of pills, condoms, and injectables. The ambassador concluded his speech by thanking all who have been supporting the country to achieve these remarkable results.

### **TRAINING STRENGTHENS CMSD WAREHOUSE MANAGEMENT**

The CMSD plays a key role in supply chain activities for the DGHS of the MOHFW. It stores and distributes health and non-health commodities for health facilities throughout the country. In its efforts to strengthen Bangladesh's health system, SIAPS is assisting in the development of standard operating procedures (SOPs) on storage and distribution for the CMSD.

On May 17, 2014, SIAPS facilitated the first consultative workshop for CMSD staff, other concerned DGHS officials, and technical personnel from development partners (World Bank, Department for International Development, WHO, UNICEF, etc.). The objectives of the workshop were to share the draft SOPs with participants; obtain feedback and recommendations on them; and incorporate the input to produce a revised draft document on the CMSD's warehouse management system. The workshop was chaired by Brigadier General Md. Golam Rasul, Director, CMSD (Director, Stores and Supplies, DGHS, and Line Director, Procurement, Logistics and Supplies Management). Participants were divided into four work groups to address the seven thematic areas of the SOPs. The groups made presentations with specific recommendations, including a roadmap for the revision, finalization, and institutionalization of the SOPs for the health facility stores of the DGHS.

## CASE STUDY: FORECASTING EXERCISE ADDRESSES OVER-STOCKING OF EXPENSIVE FIRST- AND SECOND-LINE ANTI-TB MEDICINES

The spread of TB cannot be controlled without an adequate, uninterrupted supply of first- and second-line medicines. These medications are quite expensive and the supply depends heavily on donations from the Global Fund. Proper management of TB medicines and supplies is a very important part of the NTP. The NTP must consider its medicine and laboratory supply situation from a supply chain management perspective. Accurate forecasting, timely procurement, effective store keeping, and efficient distribution are the key elements of supply chain management that contribute to effective inventory management, planning, and a regular, uninterrupted supply of quality medicines and laboratory consumables.

Understanding these concepts, the NTP formed a national Procurement and Supply Management (PSM) Unit with technical assistance from SIAPS. The WHO, BRAC, the USAID-funded TB CARE II project, Damien Foundation, SIAPS, and the NTP are partners of this central coordination mechanism. Staff from PSM and SIAPS participated in the recent Global Fund TB JMM in March-April 2014.

During this mission, the team found that a quantity of expensive second-line medicines was being stored at the central warehouse. Meanwhile, the NTP had already placed orders with the Global Fund for the same medicines without undertaking any validation or making necessary periodic adjustments in the expected and actual enrollment of patients. Another problem identified was the lack of adequate coordination between program and operations staff. These findings compelled the NTP to immediately undertake a forecasting exercise in April 2014 covering the period April 2014 to March 2015, with technical assistance from SIAPS.

The SIAPS technical team undertook the forecasting exercise using QuanTB (and using the morbidity method), in consultation with WHO, BRAC, clinicians, the Damien Foundation, and the NTP. The team collected all the necessary data and reviewed key documents, including standard treatment guidelines, census data, TB prevalence survey data, national guidelines, strategic papers, routine annual and quarterly reports, the Global Drug Facility (GDF) order management system, the PSM plan, and case data in e-TB Manager. The team generated a couple of programmatic scenarios and created seven alternative regimens to address the overstock situation. The team also analyzed the actual versus expected enrollment in the past and gained consensus on expected patient enrollments by regimens. The results of this extensive exercise showed that the amount of stock for some second-line medications exceeded a 30-month supply, e.g., Amx/Clv (33 months), Clf (33 months), Mfx (33 months), and PAS acid (33 months). The analysis triggered discussions among the WHO South East Asia Region, GDF/Geneva, International Dispensary Association Foundation, SIAPS, and the NTP, and contributed to the cancellation, deferment, and relocation of some of the upcoming orders to another country, as well as the introduction of alternative regimens through an official NTP notification to immediately treat multidrug-resistant and extensively drug-resistant patients. The efforts facilitated the successful relocation to the GDF stockpile of USD 899,976 worth of medicines (including reallocation of medicines to Nepal valued at USD 119,436). It is worth mentioning that the PSM Unit reviews and updates the data in QuanTB (stock on hand and on order, patient enrollments, consumption trends, etc.) on a monthly/quarterly basis and takes necessary data-informed supply chain actions to avoid potential stock-outs and overstocks of anti-TB medicines.

A second consultative workshop was held on July 3, 2014. This workshop involved a small technical work group of CMSD staff (as decided during the first consultative workshop), which included the CMSD director, deputy director, and other senior-level officials. A draft table of contents for the SOP manual was presented and technical input was obtained from participants to finalize the different sections of the document. At the end of the workshop, participants unanimously agreed on the timeline for developing the final draft of the SOPs for CMSD warehouse management.

### **PRICE GUIDANCE DOCUMENT WILL STRENGTHEN PROCUREMENT PROCESS**

To strengthen the procurement process of the MOHFW, SIAPS continued to provide technical assistance for the development of a pricing guide for medical equipment. The guide will be used primarily by line directors, who are ultimately responsible for annual procurement plans. It will help them to plan better, evaluate properly, avoid rebidding, and reduce delays in the procurement process, thereby reducing lead times. The key procurement entity, the CMSD, and others at sub-national levels of the DGHS will also benefit because they can use the guide to verify the prices offered during their evaluation of bids. A technical review of the draft was held on September 3, 2014, in which 20 technical personnel from the MOHFW participated. Representatives of the line directorates requested that SIAPS develop specifications and prices (within a limited range) of all listed medical equipment for 50- and 250-bed hospitals, which will help them with planning and for audit purposes.

Another workshop to finalize the pricing guide was held on September 10, 2014, at the DGHS, involving a larger number of participants (including policy makers), DGHS line directors, directors of Dhaka-based medical college hospitals, the CMSD procurement team, and donors. The pricing guide for medical equipment was well received; suggestions for additions were offered. Key decisions made at the workshop were that country-wide training on the pricing guide should be organized for health managers and training (overseas) on the pricing guide and market dynamics should be organized for procurement entities.

### **SKILLS OF DGFP AND DGHS OFFICIALS BUILT IN FORECASTING RMNCH COMMODITIES**

A day-long training on forecasting for the 13 commodities recommended by the United Nations Commission for Life-Saving Commodities for Women and Children was organized by the PLMC of the MOHFW. It was facilitated by SIAPS on September 11, 2014, in Dhaka. The objective was to build the capacity of relevant DGFP and DGHS officials in forecasting processes for RMNCH commodities using globally approved algorithms and an Excel-based tool. The event was chaired by Mr. Md. Shamsuzzaman, Program Manager, PLMC, MOHFW. During the training, participants were oriented to different forecasting methods and learned the principles of forecasting and supply planning processes. They were also oriented on how to choose the appropriate forecasting method depending on the availability of data and analysis capacity; and the different stages or policy scenarios involved in forecasting for RMNCH commodities. During the training and as part of sustainability planning, SIAPS proposed that the PLMC take the lead role in forming a “national RMNCH quantification working group” (involving DGFP and DGHS technical experts) so that it could do the forecasting on its own. This proposal was well received by the participants, with many of them expressing interest in being part of the working group. It was decided that the MOHFW will send a letter to the line directors (MNCH) of the DGHS and DGFP requesting their consent to the names proposed and any recommendations for inclusion of relevant officials from the respective directorates. Once decisions have been reached and as a follow-up, SIAPS will take the necessary steps to build the capacity of members of this new working group.

### **USE OF E-TB MANAGER EXPANDS TO 100 ADDITIONAL SITES**

The sixth Joint Monitoring Mission (JMM) of the National Tuberculosis Control Program (NTP) recommended that e-TB Manager, a web-based tool for the programmatic management of TB and drug-resistant TB, be expanded throughout Bangladesh to improve the recording and reporting of TB cases. In response to this recommendation, the NTP decided to

roll-out e-TB Manager to 100 new sites, with technical support from SIAPS. The sixth JMM, in which SIAPS actively participated, reviewed progress in TB prevention, care, and control and offered guidance on future TB control directions and efforts in Bangladesh. SIAPS assisted NTP to prepare a roll-out plan for e-TB Manager, including a plan to track the process. SIAPS also had a meeting with the Damien Foundation, Lepira, HEED (Health, Education, and Economic Development) Bangladesh, and the Urban Primary Health Care Services Delivery Program, the implementing TB partners at the newly selected sites. The purpose of this collaboration was to decide on specific responsibilities of partners to implement and monitor e-TB Manager and ensure its sustainability at the new sites.

According to the roll-out plan, a training of trainers (TOT) workshop on e-TB Manager was organized by the NTP and facilitated by SIAPS on May 27-29, 2014. Participants included NTP officials, four TB implementing partners from selected sites, and the four best performers from different upazila health complexes (identified by the NTP and SIAPS based on their proficient use of e-TB Manager over the last year). Following the TOT, the pool of 18 master trainers provided basic e-TB Manager training for 254 TB staff at the 100 new sites. This training was completed in August 2014. Orientations on e-TB Manager were also carried out by SIAPS for all district civil surgeons and upazila health and FP officers, as well as on SOPs for TB medicines and supplies, including the proper use of the paper-based logistics management information system format of the NTP.

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## **WE WOULD BE HAPPY TO HEAR FROM YOU**

Please send comments to Liza Talukder at [ltalukder@msh.org](mailto:ltalukder@msh.org).

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