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National PV Program Launched

Bangladesh officially launched its National Pharmacovigilance Program on September 2, 2013, at an event held in the management information system (MIS) auditorium of the Directorate General of Health Services (DGHS). Mr. M. M. Neazuddin, Secretary, Ministry of Health and Family Welfare (MOHFW), inaugurated the event by mentioning this new program as a milestone in the country's public health system. The Secretary acknowledged the remarkable accomplishment of the Directorate General of Drug Administration (DGDA) as well as the support provided by SIAPS.

A sound pharmacovigilance (PV) program in Bangladesh is not only a public safety issue, but it is critical to the development of the country's growing pharmaceutical export sector. The General Secretary of the Bangladesh Association of Pharmaceutical Industries, Mr. Abdul Muktadir, highlighted the fact that Bangladesh is one of the world's largest exporters of medicines, not too far behind India and China. Bangladesh exports pharmaceuticals to 86 countries; in 3–5 years, it will expand exports to 120 countries. According to Mr. Muktadir, only by maintaining the highest standards of safety, effectiveness, and quality can the country increase its export earnings from pharmaceuticals.

Dr. Zubayer Hussain, SIAPS/Bangladesh Country Program Director, presented the technical assistance that SIAPS will provide to support this important initiative. SIAPS is working on the guidelines for the PV program that will serve as a blueprint for implementation of priority activities. In preparation for the launch, SIAPS collaborated with MOHFW to update and standardize the reporting form for adverse drug reaction (ADR) events and will continue to work with the Ministry in collecting, assessing, and analyzing these reports.

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

Speaking on behalf of USAID, Mr. Gregory Adams, Director (Acting), Office of the Population, Health, Nutrition and Education, USAID/Bangladesh, pledged continued support of the SIAPS Program in promoting PV.

The launching ceremony was also attended by the members of the ADR Advisory Committee (ADRAC), PV focal persons from different government hospitals, officials from the DGDA, and other USAID partners.

WORKSHOP TO FINALIZE THE *PROCUREMENT OPERATIONS MANUAL* FOR MOHFW

A three-day workshop was held at the Nazimgarh resort in Sylhet, September 12–14, 2013, to finalize the *Procurement Operations Manual* (POM). The workshop was sponsored by the USAID-funded SIAPS Program. The Additional Secretary, MOHFW, chaired the workshop, which was attended by officials and desk officers from the different procurement entities in MOHFW, including the Central Medical Store Depot, Health Engineering Department, Directorate General of Family Planning (DGFP), and other line directors' offices of the DGHS. These participants, as well as the SIAPS/Bangladesh procurement team member, were the 15-member working group responsible for finalizing the POM. An observer from the Ministry of Finance also participated.

Two preparatory workshops were convened prior to this workshop. On August 31, 2013, a one-day kick-off workshop was held in the MIS auditorium of the DGHS, attended by the working group members. The purpose

WORKSHOP ON CONDEMNATION OF UNUSABLE AND OBSOLETE ITEMS

On July 7, 2013, with the assistance of SIAPS/Bangladesh, MOHFW conducted a one-day workshop in the DGHS MIS auditorium for 120 participants on the condemnation of unusable items in hospitals and medical centers throughout Bangladesh. Attendees included hospital directors, civil surgeons from all 64 districts, directors of medical colleges and specialized hospitals, and senior officials from MOHFW. Problems and plans for disposal of unusable items at different hospitals and health centers were discussed, and immediate solutions concerning this issue were sought from MOHFW.

Participants from hospitals nationwide expressed their commitment to dispose of unusable items at their facilities. Following the workshop, SIAPS facilitated de-junking at the DGFP central warehouse, making available ~3,000 square feet of critically needed storage space. To date, 42 upazila family planning (FP) stores and two warehouses have completed the disposal process.

was to review the initial POM document prepared by an international consultant and SIAPS/Bangladesh technical staff from its procurement team. On September 8 and 9, a follow-up workshop was conducted with the same participants in the MIS auditorium.

A total of 25 officials from MOHFW and SIAPS/Bangladesh attended all three workshops. The working group members thoroughly reviewed the draft manual and provided comments and suggestions, producing a final draft of the POM for MOHFW. The document is currently being vetted by the World Bank (WB) and the Central Procurement Technical Unit in the Ministry of Planning. Once comments and suggestions from these reviewers are incorporated, the POM will be finalized and used by all offices in MOHFW that undertake procurement.

MONTHLY DGFP PROCUREMENT MEETING

The monthly procurement meeting of the Logistics and Supply (L&S) Unit was held in its conference room at the DGFP on August 26, 2013. (These monthly meetings were recommended by SIAPS' predecessor project, Strengthening Pharmaceutical Systems [SPS], as a means to improve the procurement and logistics activities of the L&S Unit. They have been conducted regularly since 2010.) Mr. Kafil Uddin, Director (L&S), DGFP, and other officials from the L&S Unit, the WB, USAID and SIAPS/Bangladesh attended. There were a total of 16 participants, including 4 women. The meeting was facilitated by the L&S director and the senior technical advisor-procurement, SIAPS/Bangladesh.

The L&S Unit provided a briefing on the DGFP procurement system to orient the new WB delegation. L&S Unit staff stated that the procurement it manages, for itself and for all other units of the DGFP, is working well. The Unit gave an update on the status of fiscal year (FY) 2012–13 procurement. On average, shipments financed by the WB-funded International Development Association, the reimbursable project aid credit, and Government of Bangladesh-funded procurement have been received in 18–34 weeks, much less time than the required 58 weeks stipulated by MOHFW. This significant reduction in total procurement time has helped to assure the availability of stocks of contraceptives and other essential commodities. This result has been noted as a great success for the L&S Unit. Meanwhile, the consolidated procurement plan for FY 2013–2014 has been approved by MOHFW and the WB so that procurement activities may begin. The Procurement and Logistics Management Cell of MOHFW regularly monitors the status of procurement against procurement plans.

As for capacity building in local procurement, a need for such training has been identified for all desk assistants in the L&S Unit and other units of the DGFP; in the future, all officers may be required to attend this type of training. The need for overseas training for L&S officers was reiterated at the meeting, and will be facilitated by SIAPS/Bangladesh.

In response to learning that the SIAPS program will close in September 2016, DGFP representatives stated that they do not want the program to end. The provision of routine and regular technical assistance to DGFP officials by SIAPS staff is highly valued and should be expanded to other units of DGFP and the larger MOHFW as well.

DE-JUNKING OF OBSOLETE ITEMS FROM THE FAMILY PLANNING CENTRAL WAREHOUSE

The national family planning program has its own vertically organized warehousing and distribution system. The system has four levels: the Central Warehouse, regional warehouses, upazila FP stores, and stores at service delivery points. All logistics management systems rely on a well-functioning supply chain system to deliver reproductive health (RH) commodities and other essential medicines to the end user. A key component of the logistics management system is warehousing or storage and distribution of commodities. Poor warehousing and distribution results in shortages, stock-outs, millions of dollars lost to expired and damaged pharmaceutical products, and inefficient distribution to the periphery. Countries can reduce waste, improve the availability of products, and save money by improving their storage and distribution systems.

The Family Planning Central Warehouse (CW) was built in 1979. It has approximately 18,000 square feet of floor space and 4,000 square feet for vehicle parking. A couple years later, a two-story repacking unit was built.

The Challenge

The CW has not taken any steps over the last 34 years to condemn and destroy unusable or obsolete items, including old vehicles. Rather, many unlisted obsolete items were stored, thereby reducing the available storage space for usable products. None of the warehouse managers took the initiative to get rid of unusable items.

Interventions

Since 2010, SIAPS/Bangladesh repeatedly raised this issue, stating that the routine condemnation of unusable and obsolete items is one of the most important elements of good warehousing practices. SIAPS has:

- Facilitated several discussion meetings with the DGFP and CW authorities
- Coordinated and organized an on-site visit by high-level authorities from the DGFP
- Provided technical assistance in simplifying the condemnation process and obtaining notification
- Facilitated and coordinated revisions to the supply manual
- Incorporated a condemnation process for the CW
- Assisted in reforming the condemnation committee and developing terms of reference for the committee
- Assisted in the development of an action plan for de-junking old vehicles and unusable and obsolete items
- Supported de-junking of old vehicles, unserviceable heavy equipment, and a large number of other unusable and obsolete items
- Equipped the garage shed and repacking unit with necessary palates and shelving
- Organized empty containers to enhance storage space

Results

The CW has benefitted greatly from these efforts and is trying to ensure optimum use of the freed-up space.

- Nearly 3,000 square feet of space was made available in the garage shed to use as storage.
- The front yard of the warehouse is now empty, and vehicles can move easily to the loading docks.
- One of the closed doors may now be used as a loading dock.
- The use of vertical space has been maximized through the installation of shelving.
- 2,500 cubic feet of storage facilities were enhanced by two empty containers that are used for storing printed materials

Before de-junking

After de-junking

SIAPS HANDS OVER STOCK STATUS REPORTING SYSTEM TO THE DGFP

Since the inception of its work in supply chain management with the DGFP in January 2010, first under the SPS program and more recently under SIAPS, the need for regular documentation and reporting on the stock status of contraceptives in the country has been recognized as vital, enabling the DGFP to procure RH commodities on time and avoid stock-outs.

With this aim in mind, SIAPS developed a monthly stock status reporting system for the DGFP. The DGFP stock status report is a two-page document designed for managers and policy makers, enabling them to decide when to procure items and the appropriate quantities.

This is the fourth consecutive year that the reporting system has been in effect and that the report has been prepared. The system has received the attention of all concerned in the DGFP, the larger MOHFW, and development partners in the country because it has proven to be an important and useful tool.

In a recent L&S Unit monthly meeting, agreement was reached between the DGFP and SIAPS/Bangladesh to transfer skills and responsibility for the report to the L&S Unit from SIAPS/Bangladesh. The DGFP designated one procurement officer and one assistant in the L&S Unit to assume responsibility in a phased manner. In September, the L&S Unit prepared the report with assistance from SIAPS. The DGFP and SIAPS recognize that complete transfer of responsibility is possible but will take time. DGFP officials are committed to taking over responsibility in the near future.

SOPS FOR SUPPLY CHAIN MANAGEMENT OF TB DRUGS AND SUPPLIES

Managing tuberculosis (TB) drugs and supplies is a very important factor in the National TB Control Programme (NTP), for the success of TB control efforts nationwide. The NTP must consider the drug and laboratory supply situation from a supply chain management (SCM) perspective. Accurate forecasting, timely procurement, effective storekeeping, and efficient distribution are the main components of SCM that contribute to effective inventory management, planning, and a regular uninterrupted supply of quality medicines and laboratory consumables.

The NTP developed the first edition of the standard operating procedure (SOP) for managing drugs and supplies in 2009, with technical assistance from the Global Fund to Fight AIDS, Tuberculosis and Malaria and the World Health Organization (WHO). Because of expansion of the TB program, the SOP needed to be updated and revised. SIAPS was asked to prepare an initial draft for review by the NTP Technical Working Group (TWG). The director of the Mycobacterial Disease Control Unit of the DGHS appointed a TWG to undertake this task and then submitted the reviewed document to a wider stakeholder group for endorsement. SIAPS hired an international consultant to prepare a second edition of the SOP, which was finalized during this quarter; all comments from key TB stakeholders were incorporated through a national level workshop in April 2013.

WORKSHOP TO DEVELOP A STANDARD BIDDING DOCUMENT

Thirty desk officers from various line directorates participated in a two-day workshop on August 21 and 24, 2013, at the MIS auditorium to develop a standard bidding document under the framework agreement. Chaired by Mr. Md. Ayubur Rahman Khan, Additional Secretary, Development and Medical Education, MOHFW, the workshop was facilitated by a consultant engaged by SIAPS/Bangladesh.

The framework agreement is a special kind of long-term agreement between the lead procuring entity and sole or several supplier(s) for procurement of frequently used, specialized health, population, and nutrition (HPN) sector goods and related services. The goal is improved efficiency by using pre-authorized vendors and enabling multi-year agreements that allow for staggered and more flexible delivery schedules. Workshop participants unanimously agreed to draft standard bidding documents and requested SIAPS to prepare the draft.

ADRM CELL DECLARED AS THE NATIONAL DRUG MONITORING CENTRE

SIAPS initiated support to the DGDA in 2013 to revive dormant committees and cells in the Directorate. As a result, the Adverse Drug Reaction Monitoring (ADRM) Cell has become fully functional, with meetings taking place at regular intervals. When the ADRM Cell took up its responsibilities, it applied to MOHFW on July 22, 2013, requesting recognition as the National Drug Monitoring Centre (NDMC) for Bangladesh. On September 3, 2013, the Ministry issued a notification declaring the ADRM Cell as the NDMC for the country.

The DGDA itself is declared as the NDMC, however within the DGDA, the ADRM Cell will play the pivotal role and carry out the appropriate activities. The ADRM Cell is led by Mr. A.A. Salim Barami, Director (current in-charge). The members are Ms. Nayer Sultana, Deputy Director, DGDA; Mr. Akter Hossain, Assistant Director, DGDA; Ms. Afsana Alamgir Khan, Bacteriologist, District Tuberculosis and Leprosy; a representative from the Institute of Epidemiology Disease Control and Research; and a representative from SIAPS.

The NDMC is a necessary entity to monitor ADRs, which is an important component of PV. The DGDA is responsible for ensuring medicine safety and quality for the people of Bangladesh. To streamline and clarify the process, it is important that a team of people be designated to carry out the activities, so that they are performed properly and in a systematic manner. This will be done by the NDMC. The NDMC will also collaborate with the WHO International Drug Monitoring Centre, which will further strengthen its capacity. The overall Bangladesh health system will be improved when necessary actions are taken in response to ADR cases, thereby enhancing the provision of quality medicine to the people of the country.

TRAINING ON PV AND REGULATORY SYSTEMS FOR PV FOCAL PERSONS

As a follow-up to the launch of the National PV Program, SIAPS conducted a three-day training session (September 2-4, 2013) on PV and regulatory systems for focal persons from each of the 20 selected public and private hospitals and DGDA officials. Training sessions were facilitated by SIAPS representatives from headquarters and Bangladesh; a consultant from Washington University, Dr. Andy Stergachis; senior officials from the DGDA; a professor from Dhaka University; the Expanded Program of Immunization program manager; line director, TB; and the head, Pharmacology Department, Dhaka Medical College and Hospital.

The objectives of the training were to:

- Give an overview on PV practices and support the operationalization of guidelines and reporting forms for the ADRM Cell, ADRAC, DGDA, and other relevant stakeholders of the PV focal persons
- Conduct regulatory system training for DGDA staff, committee members, and reviewers on key and emerging regulatory topics, including the quality management system, Good Regulatory Practices (GRP), quality assurance (QA), and Good Manufacturing Practices (GMP)

The topics also included:

- Good PV practices
- Operationalizing the PV guidelines and the suspected adverse events reporting forms
- Data quality management
- Spontaneous reporting of ADR events and other sources of safety information

The PV focal persons are aware of the PV system being established in the country and have been oriented on the ADR reporting format. They also benefited by learning from one another about ADR-related activities taking place in their hospitals.

The DGDA officials had the opportunity to gain a better understanding of the common technical documents and their importance and use for ensuring GMP, GRP, and QA.

WE WOULD BE HAPPY TO HEAR FROM YOU

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