

IN THIS ISSUE

- ▶ Strengthening Namibia's Pharmaceutical Regulatory Capacity
- ▶ Leveraging technology for more efficient regulation of ARVs and other pharmaceuticals in Namibia
- ▶ Assessing the impact of facility level behavioral practices on CMS performance in the supply of ARVs
- ▶ Developing a competency framework to inform public health supply chain workforce planning in Namibia
- ▶ Institutional Support to the NHTC to Improve Quality Management Systems for the Training of Pharmacists' Assistants
- ▶ NANASO implements its Resource Mobilisation Strategy: The NAMPORT Response

UPCOMING ACTIVITIES (MARCH - APRIL 2014)

- Technical support to MoHSS for improving the efficiency of the EDT/Pharmadex server for improved ART patient and logistic related data
- Technical assistance to Health Professions Council of Namibia to implement strategies for strengthening the registration of pharmacy professionals
- Dissemination of adherence treatment literacy materials and training on new ART guidelines
- Technical Assistance to Central Medical Stores for Supply Chain Performance Improvement
- Technical support to MoHSS for EDT cascade training

Strengthening Namibia's Pharmaceutical Regulatory Capacity



From left to right: Mr. Johannes Gaeseb (Registrar of NMRC), Mr. Evans Sagwa (Acting Country Director, SIAPS/SCMS Namibia), Mr. Michael Anisfeld (SIAPS Consultant), Dr. Louis An (Technical Advisor, SIAPS/Arlington), Mr. Nasser Mbazira (Senior Technical Advisor, SIAPS/Namibia), Mr. Gilbert Habimana (Chief Pharmacist, Pharmaceutical Control & Inspection). Photo by MSH staff, Namibia.

In 2009, the USAID-funded Strengthening Pharmaceutical Systems (SPS) programme provided technical assistance to the Namibia Medicines Regulatory Council (NMRC) to conduct an assessment and gain a better understanding of how the institution functions as a medicines regulatory body, and provided recommendations on how they could improve their pharmaceutical regulatory processes.

Recently, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) provided further technical assistance by conducting a follow-up holistic review of the NMRC to establish what progress had been made during that time period, and agree with the NMRC on how and where SIAPS should focus their attention.

The review, which was conducted in January 2014, focused on NMRC systems for pharmaceutical registration, licensing and inspection of the

pharmaceutical distribution chain, therapeutics information and pharmacovigilance, and the surveillance of the quality of medicines. Although NMRC had made progress in implementing the recommendations from the 2009 assessment, there were some areas where they experienced challenges.

A major challenge that the institution continues to face is a shortage of technical staff, limited by the staffing structure of the NMRC and their inability to attract and retain new hires. Consequently, this hinders the successful implementation of their operations. The lack of adequate human resources has placed a huge workload on the current few NMRC staff, rendering them unable to effectively implement recommended Standardised Operating Procedures (SOPs) and guidelines. In addition, the managerial staff are compelled to spend more time on actual technical activity implementation at the expense of administrative duties. Finally,

Continued on page 2 →

Leveraging technology for more efficient regulation of ARVs and other pharmaceuticals in Namibia

Antiretroviral medicines (ARVs) and all other pharmaceuticals need to be assessed for their quality, safety and efficacy before they are registered for distribution and use in Namibia. The Systems for Improved Access to Pharmaceuticals and Services (SIAPS), a five-year USAID and PEPFAR-funded, MSH-led project has been providing technical assistance to the Namibia Medicine Regulatory Council (NMRC) to effectively perform its mandate of regulation of ARVs and other pharmaceuticals in the country.

The availability of quality, safe and efficacious ARVs, including new ARV pediatric formulations and other essential medicines cannot be achieved without an efficient and effective pharmaceutical registration process.

By using a simple desktop Microsoft Access-based tool called Pharmadex® that was initially developed by the USAID-funded Strengthening Pharmaceutical Systems (SPS) project in 2007 and improved upon by SIAPS, NMRC staff are able to electronically capture information about pharmaceutical companies regarding their applications (dossiers) for the registration of a particular product; to easily organise the information; and to track the review process by displaying the timelines for each application under review.

However, due to a limited number of staff, the NMRC has continued to face a backlog of applications and increased registration process time, which could adversely affect the antiretroviral therapy (ART) outcomes if new ARV formulations are not readily available in Namibia due to delayed registration. Thus, in 2014, the desktop



A snapshot of the web based PharmaDex® graphical user interface (GUI). Note that the depicted GUI is yet to be finalized with Namibia specific content

Pharmadex® tool was updated to a web-based version, which shifts the responsibility of entering administrative information directly to the pharmaceutical companies themselves, thereby freeing up more time for NMRC technical staff to evaluate the products dossiers. In addition, the web-based Pharmadex® tool will improve transparency and accountability throughout the medicines registration process.

In January and February 2014, SIAPS provided technical assistance to the NMRC towards deployment of the web-based version of Pharmadex®. SIAPS conducted a demonstration of the upgraded Pharmadex® tool to the NMRC staff and gathered their feedback regarding required modifications to better adapt the tool to the NMRC needs.

The upgraded tool was very well received and preparations for the trial phase of the tool by the NMRC staff and select pharmaceutical companies are underway. During the trial phase, the NMRC will begin to process received applications using the new web-based version and the selected local pharmaceutical companies shall apply for the registration of their products online. We anticipate that the new Pharmadex® will ease some of the administrative burden currently placed on the NMRC technical staff and expedite processes for the registration of ARVs including pediatric formulations and other essential medicines.

Contributed by: Louis An, Utkarsh Srivastava, Evans Sagwa, Samson Mwinga and Nasser Mbaziira (SIAPS Pharmadex technical team)

Strengthening Namibia's Pharmaceutical Regulatory Capacity

Continued from page 1...

budgetary deficits have also hindered progress in some areas. To help alleviate the severe human resources challenges, SIAPS will be providing technical assistance to the NMRC to train persons from the public sector, the private sector, and the University of Namibia in:

- Pharmaceutical dossier evaluation
- Good Regulatory Practices (GRP)
- The Common Technical Documents (CTD) for medicines registration
- Good Manufacturing Practices (GMP) inspections
- Good Distribution Practices (GDP) inspections
- Quality Management Systems (QMS) for the testing of the quality of pharmaceutical products in Namibia.

This pool of trained persons will be engaged through various mechanisms to assist the NMRC in accomplishing its pharmaceutical regulatory mandate so that quality, safe and efficacious ARVs and other essential medicines are available in the country.

Contributed by: Louis An, Nasser Mbaziira and Evans Sagwa (SIAPS technical team)

Assessing the impact of facility level behavioral practices on CMS performance in the supply of ARVs

In January 2014, SIAPS/Namibia supported the Ministry of Health and Social Services (MoHSS) to identify those health facility level behavioral practices that impact on the Central Medical Store (CMS) performance in the supply of antiretroviral medicines (ARVs).



Prof. Diana Bowser of the Harvard School of Public Health interviewing enrolled nurse, Maria Titus, at Aroab Health Centre. Photo by MSH staff.

Increasing incidents of stock out of key ARVs at facility level, low service level performance from central medical stores,

repeated call for facilities to accurately forecast and plan for supply of medicines have necessitated a need to identify challenges and gaps in the end-to end supply chain system in the country.

In view of this, SIAPS, in conjunction with the Pharmaceutical Services Division of the MoHSS engaged two experts from the Harvard School of Public Health—a SIAPS partner—to conduct a comprehensive behavioral practice assessment of the impact of facility level inventory management practices on CMS performance in the supply of ARVs in Namibia. The report of the assessment is still being compiled but the findings will guide future interventions in ensuring that good pharmaceutical management and sound inventory practices at health facilities are adhered to for ARVs and other essential medicines.

Contributors:
Greatjoy Mazibuko, Wolde Alemayehu, Benjamin Onger, Evans Sagwa and Harriet Kagoya (SIAPS and SCMS Namibia)



Prof. Diana Bowser of the Harvard School of Public Health interviewing a registered nurse, Katherene Musiyoka, at the Rosh Pinah Health Centre. Photo by MSH staff.

Developing a competency framework to inform public health supply chain workforce planning in Namibia

The optimal performance of the supply chain for antiretroviral medicines (ARVs) is dependent on having adequate numbers of competent, recognized and empowered health supply chain workforce.

In January and February 2014, the PEPFAR-funded USAID project, SCMS collaborated with the people that deliver (PtD) initiative to map out the tasks and behavioural competencies of different cadres of staff having supply chain responsibilities in Namibia.

The activity involved a stakeholder's workshop to validate the draft PtD public health supply chain competency compendium within the Namibian context and also brainstorm on cadres involved in specific competency areas. The workshop drew participants from the Ministry of Health and Social Services (MoHSS)'s division of pharmaceutical services and the division of the human resources policy and planning. Other participants came from the University of Namibia's School of Pharmacy, the Namibia-German Centre for Logistics (NGCL) of the Polytechnic of Namibia and the National Health Training Centre (NHTC).



In the foreground, Erin Hasselberg, SCMS Principal Advisor on Human Resource Capacity Development (standing, right) facilitates a discussion with Central Medical Store staff, Seija Nakambela (standing, middle) and Tonata Ngulu (seated), on one of the supply chain competency domains at the public health supply chain workforce stakeholder's workshop held in Windhoek on January 28, 2014. Photo by MSH staff, Namibia.

Follow-up interviews and focus group discussions were held with front-line staff at CMS and the RMS in Oshakati to develop a detailed task and competency map.

The resulting competency framework will detail the tasks and behavioural competencies of pharmacists, pharmacists' assistants and clerks with supply chain responsibilities in Namibia.

It will be used to guide the application of the World Health Organisation's human resource management tool, 'Workload

Staffing Need (WISN)' by IntraHealth /CapacityPlus, a PtD member organisation collaborating with SCMS, to determine staffing requirements and the appropriate skill mix. Ultimately, the outcome will inform future decisions on supply chain staffing, job descriptions, education, and training with an end goal of improving the public health supply chain performance in Namibia.

Contributed by Benjamin Onger
(Senior Technical Manager, SCMS)

Institutional Support to the Namibia Health Training Centre (NHTC) to Improve Quality Management Systems for the Training of Pharmacists' Assistants

SIAPS is continuing to support building of the institutional capacity of the Namibia Health Training Centre (NHTC), by strengthening the systems for assuring the quality assurance of pharmacists' assistants (PAs) trained at the institution. This is in line with the requirements of the Namibian Qualification Authority (NQA), a statutory body for regulating the quality of all qualifications granted by training institutions in the country. NHTC is the only institution that is training PAs in Namibia.

In February 2014, SIAPS/Namibia installed at NHTC's PA training unit a computer local area network (LAN) comprising of a server with several

dummy terminals that are accessible by PA students and their tutors through password protected user profiles. The LAN is fitted with the electronic dispensing tool (EDT) for training PA students on patient and stock management for patients on antiretroviral therapy (ART). In addition to this, PA students and their tutors can use the terminals for their assignments and lesson plans respectively, and for maintaining training records. This LAN will effectively provide a platform for "learner"- "tutor" exchange of training materials and relevant literature in the course. It will also serve as a database for student records, academic transcripts and related files. This support has been welcomed by NHTC management as an

important step in strengthening quality assurance of the PA training program at the institution. Within the same month, the NHTC with support from SIAPS/Namibia obtained final approval of the PA training curriculum from the Health Professions Council of Namibia, which was previously developed with technical assistance for the USAID-funded Strengthening Pharmaceutical Systems project. This was a major endorsement by the professions regulatory body on the quality and depth of the curriculum developed through USAID funding.

Contributors:
Greatjoy Mazibuko, Evans Sagwa and Stanley Stephanus
(SIAPS Namibia)

NANASO implements its Resource Mobilization Strategy: The NAMPORT Response

In October 2013, the USAID-funded Building Local Capacity (BLC) project supported the Namibian Network for AIDS Service Organisations (NANASO) to develop a resource mobilisation strategy to contribute towards its efforts of ensuring sustainable funding and reduced donor dependency.

NANASO is an umbrella agency mandated to raise the profile of HIV and AIDS civil society organisations (CSOs), facilitate members' capacity building, advocate for, and link members to current information and resources on HIV/AIDS. NANASO has and is still experiencing challenges in acquiring financial resources to sustain itself and to support its members. One of the strategies that the organisation aggressively explored and implemented following the development of its resource mobilisation strategy was to mobilise the public sector to invest in HIV and AIDS service delivery.

From November 2013 to February 2014, NANASO has received an encouraging response as well as a donation to their fundraising gala dinner from NAMPORT, a state owned organization. NAMPORT is operating as the National Port Authority in Namibia since 1994 and manages the two sea ports of Walvis Bay and Luderitz. NAMPORT has donated N\$50 000-00 to the event.

Mr. Bisey Uirab, the Chief Executive Officer of NAMPORT, expressed the company's gratitude in being able to support HIV and AIDS infected and affected people through this partnership with NANASO. He handed over the donation to NANASO on the 28th February 2014 at an event which was attended by the Executive Director of NANASO, Mr. Sandie Tjaronda, two of NANASO's board members, Mrs. Liz Sibindi from NAMPORT, as well as the NANASO staff. NANASO has a food bank where staff and stakeholders can donate any non-perishable food items to be given as nutrition support to people living with HIV especially those on antiretroviral therapy.

Contributed by:
Ndeshiteelela Conteh and Rachel Basirika (BLC, Namibia)



Mr. Uirab, the CEO of NAMPORT, handing over the cheque of N\$50,000 to Mr. Sandie Tjaronda, the Executive Director of NANASO, while Alfred Tjiroze; NANASO board member (far left), Ronney Mutjavikua; NANASO board member (far right) and Liz Sibindi; NAMPORT Communications Manager looks on. Photo by MSH staff, Namibia.

ABOUT THE NEWSLETTER

The SIAPS/SCMS/BLC Namibia e-Newsletter is a bi-monthly newsletter that keeps you abreast of activities funded by the USAID and implemented by MSH Namibia.

Key focus areas are HIV/AIDS Management:

- Strengthening Health Systems
- Capacity Building
- Human Resource Development

Editorial Team:

- Mr. Lazarus Indongo (MoHSS)
- Mr. Evans Sagwa (MSH)
- Mr. Benjamin Ongeru (MSH)
- Ms. Harriet Rachel Kagoya (MSH)

Your contribution to this valuable communication medium would be highly appreciated and can be e-mailed to esagwa@msb.org

DISCLAIMER:

This newsletter was made possible through support provided to Management Sciences for Health (MSH) by the U.S. Agency for International Development, under the terms of cooperative agreement number AID-OAA-A-11-0002, and contract numbers GPO-A00-05-00024-00 and GPO-I-00-05-00032-00. The opinions expressed herein are those of the author (s) and do not necessarily reflect the views of the U.S. Agency for International Development.