

Supply Chain Performance Improvement Program at the Central Medical Store in Namibia

Results and Recommendations from the collaboration of the "People that Deliver" Initiative, the Ministry of Health and Social Services, SCMS and Capacity *Plus*

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About SCMS

The Supply Chain Management System (SCMS) was established to enable the unparalleled scale-up of HIV/AIDS prevention, care and treatment programs in the developing world. SCMS procures and distributes essential medicines and health supplies, strengthens existing supply chains in the field, and facilitates collaboration and the exchange of information among key donors and other service providers. SCMS comprises 13 international organizations. The project is funded by the US President's Emergency Plan for AIDS Relief (PEPFAR) and managed by the US Agency for International Development, under the terms of contract number 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 US Agency for International Development or the US government.

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Supply Chain Management System

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Acronyms

AIDS Acquired Immunodeficiency Syndrome

ART Antiretroviral Treatment

ARVs Antiretrovirals

CMS Central Medical Store

DCE Discrete Choice Experiment

DPS Division of Pharmaceutical Services (under MoHSS)

EMLC Essential Medicines List Committee

FIP International Pharmaceutical Federation

GDP Good Distribution Practices

GWP Good Warehousing Practices

GRN Goods Received Note

HR Human Resources

HRH Human Resources for Health

IHS Imperial Health Sciences

ISO International Organization for Standardization

KPI Key Performance Indicator

MOHSS Ministry of Health and Social Services

MRMD Multi-Regional Medical Depot

NEMLIST Namibia Essential Medicines List

NGCL Namibian-German Centre for Logistics

NMPC National Medicines Policy and Coordination (sub-division of Pharmaceutical

Services)

NQA Namibia Qualifications Authority

PA Pharmacist assistant

PCI Pharmaceutical Control and Inspection (sub-division of Pharmaceutical Services)

PH Public Health

PMIS Pharmaceutical Management Information System

PoN Polytechnic of Namibia

PtD People that Deliver

QA Quality Assurance

QMS Quality Management Systems

RMS Regional Medical Store

SCM Supply Chain Management

SCMS Supply Chain Management System

SCPI Supply Chain Performance Improvement

SHE Safety, Health and Environment

SOP Standard Operating Procedure

USAID United States Agency for International Development

WHO World Health Organization

WOM Warehouse Operations Management

WISN Workload Indicator of Staffing Needs

Executive Summary

The purpose of the Supply Chain Performance Improvement Program (SCPI) was to build capacity in Central Medical Store (CMS) staff in ISO-accredited warehousing best practices through a modular, adaptable three-phased approach. The need for local, country-specific training programs is in high demand. In response to increasing requests, including a request from the Namibia Ministry of Health and Social Services (MOHSS), for a more country-specific, less resource intensive warehouse operations management (WOM) course, Supply Chain Management System (SCMS) staff designed the SCPI program. For years, the traditional capacity building approach in WOM was off-site, in-service training for central and regional medical store staff around the world. Staff would leave their posts for weeks at a time, usually with travel fees and course tuition funded by donor agencies. When staff returned to their posts, it was difficult to apply what they had learned in the state-of-the-art warehouse training facilities to their own unique warehouse environments.

The SCPI program was designed to be rolled out over six months in three phases: Initiation, Onsite Training and Post Review (refer to Figure 1). In the Initiation Phase, program staff assess the performance of the current system (a central medical store or another nominated system), identify and/or establish baseline metrics and then work with the system's owner(s) to set performance metric targets. Additionally in this phase, a local academic or training institution is identified that is able to assist with local accreditation of the SPCI program in line with local legislation. This institution will address capacity building needs of the staff of the identified system.

In the Onsite Training Phase, the SCPI program deploys the tailored training interventions with a focus on staff ability to meet identified key performance indicators (KPIs). At the end of the implementation period (approximately six months), the Post-Review Phase occurs, when a team evaluates performance improvements against the baseline measures of the KPIs. At this point, program materials are also transferred to the identified local partner.

Figure i: SCPI Program Phases



Namibia was the first country to pilot the SCPI program in its entirety. Implementing the SCPI program in Namibia was a natural complement to the Competency Mapping Exercise, which was conducted in January/February 2014. The exercise identified a full set of competencies for CMS and Regional Medical Stores (RMS) pharmacists, pharmacist assistants and clerks/administrative officers, making it possible for the SCPI program to be tailored to address those specific competencies

outlined for CMS and RMS staff. The SCPI program in Namibia aimed to enable CMS management to achieve the following:

- Identify non-compliance within warehouse operations and prioritize tasks to promote change in non-compliance areas
- Leverage change management processes to ensure sustainability of the applied changes
- Identify capacity development needs for CMS staff in order to improve capabilities in stateof-the-art warehouse regulations and requirements
- Identify KPIs against which CMS performance could be benchmarked over the course of the SCPI program and beyond

Specific expected outputs of the Namibia SCPI Program as a result of the above-mentioned achievements include:

- Updated Standard Operating Procedures (SOPs) and process flows in line with ISOstandards and World Health Organization (WHO) Good Warehousing Practices
- Updated job descriptions
- Increased staff capacity to implement tasks and activities as outlined in the SOPs
- Improvements in KPI and self-inspection checklist as a result of increased staff capacity, as well as an organizational cultural shift to value systems

Implementation of a Quality Management System (QMS)

SCMS, through its South Africa warehousing and distribution partner, Imperial Health Sciences (IHS), designed SCPI to be rolled out over three phases. However, during the initial management meetings to outline the scope of SCPI in Namibia, the SCMS team (including Management Sciences for Health, the SCMS-Namibia project implementer) proposed a few adaptations to the originally designed SCPI program to best suit the needs and staffing structures of Namibia. Figure 1 visually displays the modified four phases, timeline and components of the SCPI Pilot Program and how it was modified for Namibia. Given the ongoing challenges occurring at central level, the SCPI program in Namibia focused primarily on the CMS level and staff to start.

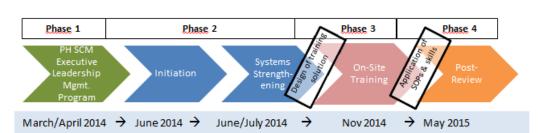


Figure ii: SCPI Program Pilot Phases Modified for Namibia

The four-phase methodology includes a series of activities briefly described in Table 1.

Table i: SCPI Activity Descriptions by Phase

Phase	Activity	Description
1	Public Health SCM Executive Leadership Management Program	Equip the newly hired CMS managers with essential management and leadership competencies, based on pharmaceutical supply chain principles, for effective stewardship of the SCPI program implementation.
2	Initiation	Outline the key components of SCPI with the main stakeholders. Complete the "SCPI Self-Inspection checklist" (see Annex 13) to assess CMS compliance on 251 different supply chain areas and record a baseline for CMS performance. Select and prioritize activities to address identified gaps and design onsite training curriculum to overcome those gaps. [Note the spirit behind the self-inspection is that CMS would be able to complete the inspection themselves. In this activity the consultants modeled how to implement the checklist].
	Systems Strengthening	Meet with CMS management to review and update systems and procedures critical to ongoing training and capacity building, including process flows, SOPs, quality management and job descriptions. Establish KPIs for the overall SCPI program in Namibia. Identify incountry SCPI academic training partner to accredit and also continue the SCPI training offering in the future.
	Design of Training Solution	Adapt existing SCPI warehousing best practices curriculum, based on ISO, WHO, GWP/GDP standards, to address the identified CMS gaps and suit the varying competency levels of CMS management and staff.
3	Onsite Training	Provide onsite competency-based two-week training within the physical warehouse, alternating between theory-based training sessions in a classroom format and practical sessions in a warehouse setting under supervision of trainers, managers and supervisors.
4	Post Review	Assess how well staff at CMS implemented the methodologies and processes in which they were trained. Complete a follow-up of the SCPI Self-inspection Checklist and analyze KPI measures established in the Initiation Phase to determine system improvements. Share results with stakeholders and CMS senior management to help direct ongoing implementation of best practice standards at CMS in the future.

Findings and Recommendations

Over the course of four different phases in just over twelve months, the SCPI program gained extensive insight into the operation of the Namibia CMS, particularly the distribution section, and made significant strides in building the capacity of the CMS supply chain workforce. This first-ever pilot of phased performance improvement spanned a wide range of concepts and activities, from

executive leadership engagement and SOP development to interactive, competency-based training activities. The findings and recommendations contain valuable information to other countries attempting similar performance improvement activities.

Findings

At the conclusion of the Post-Review phase, the impact of SCPI was evident in the quantifiable improvement in the established key performance indicators (KPIs), as compared to baseline measurements. In addition, the qualitative data included numerous lessons learned from this initial pilot. In addition to facilitating the progress measured by the KPIs, the consultants with the SCPI program successfully completed the following for CMS:

- Reformatted and updated existing SOPs as well as the development of core SOPs (e.g. Operational, Quality and Health and Safety SOPs). Quality and Health and Safety SOPs were not previously available at CMS.
- Reviewed and redesigned all process flows, including:
 - o Receiving and Acceptance Procedures: Cold Chain
 - o Receiving and Acceptance Procedures: General Pharmaceutical and Clinical Supplies
 - o Receiving and Acceptance Procedures: Security Products and Schedule 4
 - o Put away Process
 - o Order Capture Procedures
 - o Picking Procedures
 - o Packing and Checking Procedures
 - o Dispatch of Customer Order Procedures
- Reformatted and updated job descriptions to include a focus on KPIs and developed future
 job descriptions based on Competency Mapping findings to be used when CMS staffing
 structure is updated.
- Designed a Quality Manual and a Health and Safety File, enabling effective quality management of services and products.
- Designed a Site Master File, readying CMS for any inspection.
- Tailored an existing two-week onsite training curriculum (Annex 6 includes a detailed outline of the two-week curriculum, including session objectives).

Progress against Key Performance Indicators

• Percentage of self-inspection checklist items found to be compliant

The SCPI program facilitated a 39% increase in compliance. During the initiation phase, 84 out of 251 areas inspected (33 percent) were found to be compliant; however, by the completion of SCPI, compliant areas increased to 180 out of 251 areas inspected (72 percent).

Percentage of functions completed according to SOPs

This KPI was not originally measured at the baseline, as the SOPs were not fully implemented or documented at CMS. SCPI required a comprehensive review and update of all SOPs for the distribution section. During the Post-Review phase, a consultant conducted interviews with the individuals responsible for the various areas (receiving, warehouse and dispatch) in the distribution area, and through observation confirmed the interview findings to complete the SOP implementation checklists. On the completion of this intervention, CMS SOP compliance rates ranked at the following percentages:

- o Operational SOPs: 96 percent
- o Quality SOPs: 55 percent (these were newly developed SOPs for CMS)
- o Health and Safety SOPs: 42 percent (these were newly developed SOPs for CMS)

• Order fulfillment rate

From the initial baseline measurement at the start of the SCPI Program, CMS order fulfillment rates for ARVs were at an all-time low of 77 percent in Q4 of FY14, but gradually increased to prior levels of over 90 percent in Q2 of FY15 during the post-review (See Figure 3). The order fulfillment rates (also known as service levels) for other essential medicines, however, did not rise above the "acceptable" level of 80 percent over the entire year. While the ARV fulfillment rate increased, SCPI likely did not have an impact on either ARV or other product fulfillment rates, as the underlying cause of the lower rates was related to the absence of long-term contracts with suppliers. This absence resulted in multiple requests for quotations and long order replenishment cycle times—two areas in which the SCPI training program did not focus, but which presented great challenge for CMS throughout the entire implementation of SCPI.

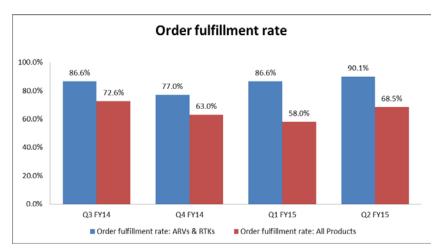


Figure 3: Order fulfillment rate

• On-time delivery rate from central to lower level

From an all-time low of 14 percent in the third quarter of 2014, CMS on-time delivery for orders to health facilities improved remarkably, to 100 percent (See Figure 4). This was the result of multiple factors, including the SCPI program. Additionally, CMS recruited new drivers, workhands and pharmacists, and also instituted weekly distribution staff meetings. As a result of the 2014 procurement crisis, the Deputy Permanent Secretary attended the weekly CMS management meetings. Increased capacity building, coupled with active management and oversight, surely contributed to the rise in on-time delivery rates.

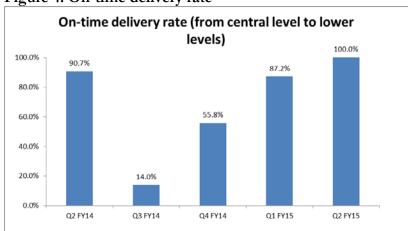


Figure 4: On-time delivery rate

Lessons learned

Central to the success of any SCPI program is continuous local buy-in and stewardship of the SCPI initiative at all phases. The SCPI program is by nature designed to facilitate an organizational shift in thinking. The change management process requires both senior management and front line management buy-in and stewardship that must be sustained throughout the phases of the program. The executive leadership program created the awareness for change and buy-in among senior CMS management and was a valuable addition to the SCPI program.

A flexible structure allows for a more tailored performance improvement solution. The SCPI framework provides a state-of-the art, flexible structure that can be adapted to a variety of existing circumstances affecting a CMS or RMS. For example, in the original design, the Initiation Phase would have led directly to development of the training curriculum and delivery of the onsite training. In the context of Namibia, after the initial assessments and visit, CMS leadership indicated their desire to rethink some of their systems before launching into training.

In order to facilitate this welcome internal look at systems, IHS consultants adapted the SCPI model to include a "Systems Strengthening" assignment to review a number of systems and procedures critical to ongoing training and capacity building including process flows, SOPs, quality management and job descriptions. The training curriculum was then updated to reflect this new focus; namely, the need for updated documentation required by Good Warehousing Practices (GWP) and Good Distribution Practices (GDP), including a new Quality Management System, Site Master File, new

Warehouse Audit documents, revised SOPs, and updated Occupational Health and Safety Procedures.

A pre-SCPI assessment may help in planning and budgeting. While the SCPI program was flexible and adaptable, any changes, such as adding a systems strengthening component, are likely to significantly impact the scope and timelines, and subsequently, the program budget. A pre-SCPI assessment may be necessary to thoroughly review the local client environment and systems before designing the adaptation and budget for the actual SCPI activity.

Overall staff morale will affect the effectiveness of the SCPI program. Management buy-in for change is important, but staff buy-in and morale is equally important. At the onset of the training, it was clear that the staff morale was low. Facilitators ensured that issues were discussed openly between management and staff, and recommendations were made incorporating input from all sides. Staff would not have been open to change if the benefits of the change were not communicated clearly.

The existing organizational structure of CMS affects the change management process. The organizational and management structure of a given CMS is unique to its respective country. There is a varying level of autonomy of each CMS, and a range in the kind of control that managers can exercise over certain functions such as procurement and resources including staff deployment, training and performance management. To achieve sustainable institutional change and performance improvement, where CMS is embedded within the Ministry of Health and under the civil service structure as in Namibia, requires coordinated involvement and support of a multiplicity of actors, some of who are outside CMS or the Ministry of Health. This level of coordination is not always possible to achieve and may therefore affect the results of the program.

Practical application and evaluation is critical to a comprehensive training program. While the classroom-based training was completed and beneficial to staff, due to the ongoing procurement crisis and delivery delays, the onsite training component of Phase 3 was not entirely completed. While classroom learning was beneficial, the on-the-job application of newly gained skills is extremely important and would ensure that the new skills are ingrained into participants' understanding and are monitored continuously over time by management.

In-country certification of the SCPI is important and can be challenging. The in-country certification of the SCPI provides local credibility to the program. Currently, the SCPI program is accredited by the South African Department of Higher Education and demonstrates in-country ownership through a partnership with a local South African University that has aligned the training content with the requirements of the Department. In South Africa, the complete SCPI program contributes 30 percent of the credits required for a Bachelor's degree in Logistics. SCPI aims to align itself with other African universities in order to ensure the local availability and sustainability of the program.

Efforts to accredit the SCPI with the Namibian German Centre for Logistics (NGCL) at the Polytechnic of Namibia (PoN) were not immediately successful due to changes in leadership at the NGCL. There was also some reluctance by the PoN to invest in accreditation of the course with the Namibia Qualifications Authority (NQA) without being assured of the demand for the course

through a commitment from the MoHSS. A key lesson learned here is that in-country certification is a lengthy process requiring technical support to the targeted institution to build a business case that will justify the investment needed to introduce and accredit a new course.

Recommendations

It is recommended that several issues be addressed by management, both at CMS and within the higher levels of the MoHSS. These include the following:

Elevate CMS to become a Directorate under the MoHSS. This strategic move will allow CMS to gain some autonomy and flexibility to adopt best practice activities and behaviors. This will also elevate SCM issues to the senior management level, enabling more effective advocacy for resources and resolution of supply chain bottlenecks, such as those currently plaguing the procurement of medicines. With this elevation, it is expected that human resources performance management will be accorded greater attention with dedicated staff to coordinate staff recruitment, deployment, on-boarding and performance appraisal, including disciplinary matters and separation, and retention and performance incentives.

Review the staff structure to establish posts for some critical areas of responsibility. The following recommended positions are required at CMS to ensure a well-functioning central medical store and to promote accountability (draft job descriptions for these positions have already been designed):

- Head of CMS (Director): Provides overall strategic direction for CMS while the Chief Pharmacist takes the role of the Responsible Pharmacist
- Inventory Manager: Focuses on monitoring the inventory across the entire supply chain, forecasting future requirements and supply planning
- Quality Assurance Pharmacist: Assumes responsibility for the QMS, including undertaking self-audits and instigating corrective actions

Implement continuous professional development and mentorship for CMS management and staff. It is important that the current management of CMS receive support to ensure that they will be successful in carrying out their required functions. This support includes leadership and management development and a dedicated mentor to help ensure introduce and/or reinforce the required management skills and self-confidence in a timely fashion. Additionally, CMS staff would benefit from more regular monitoring and supervision of their performance and opportunities for professional advancement.

Maintain weekly staff meetings. It is extremely important that the management of CMS engage with its work force regularly. This will ensure that CMS management and team members can openly discuss and learn about successes and challenges in their work environment.

Hold compulsory SOP refresher training annually for CMS; extend to RMS. SOPs need to be reviewed annually and staff trained to ensure that all CMS staff members are informed of any changes or updates to SOPs, and so that any new staff can gain the appropriate skills and implement SOPs effectively. More frequent (monthly and on a rotational basis) SOP training that take a hands-on approach will ensure that the correct procedures are followed and that quality standards are

maintained within CMS. Regular SOP trainings will also need to be extended to RMS. SOPs will need to be revised for RMDs and SOP training also extended to RMD staff.

Continue engagement with local training institutions to offer SCPI certification. Given the already established logistics and supply chain training capacity at the PoN, it is recommended that MoHSS pursue a memorandum of understanding with the NGCL to clarify the way forward for the SCPI. Alternatively, the MoHSS may consider engaging with other local private academic institutions, as these may have a more flexible decision-making structure in terms of the introduction of new courses and may be able to pursue the accreditation of the course materials with the NQA. Having a local SCPI training partner will provide the MoHSS with a sustainable solution for capacity building in SCM of health commodities.

I. Background

"People that Deliver" Collaboration in Namibia

The 2006 World Health Report described the global health crisis and highlighted the pertinent need for a competent, recognized and empowered health supply chain workforce to ensure that requirements are forecasted and supplies procured, transported, stored, distributed and dispensed to the people who need them (WHO 2006). Addressing this need, the People that Deliver (PtD) Initiative (www.peoplethatdeliver.org) was launched in June 2011 in Geneva during a WHO global consensus meeting. Since then, PtD has successfully begun to raise awareness of human resources (HR) challenges for SCM not only in the SCM community, but also in the human resources for health (HRH) community. The Initiative's board includes representatives from public, private and academic institutions, as well as high-level Ministry of Health officials from three of PtD's seven focus countries¹.

The Initiative focuses on country-level action, and the priority is to develop, test and refine guidance for country-level stakeholders on how to strengthen their country's SCM workforce. USAID/Washington, as part of its support for PtD and in collaboration with selected USAID missions, agreed to provide management and financial support through its implementing partners for this effort.

PtD followed a "bottom up" approach that entailed the implementation of a set of strategic activities in a country that is already actively engaged in health workforce efforts, which ideally include SCM (especially in larger workforce efforts), and is ready to become an active partner in the implementation process. Namibia — recommended by then-PtD Board member Mrs. Paulina Nghipandulwa, Director of Tertiary Health Care and Clinical Support Services for the MoHSS in Namibia, which has oversight over the Division of Pharmaceutical Services (DPS) — proved to be just that partner.

Mrs. Nghipandulwa, a strong advocate for HR for SCM, recommended Namibia as a focus country to test a "proof of concept" suite of HR for SCM strengthening activities, given the HR for SCM challenges experienced by CMS and RMS in particular. Namibia was also confident to undertake these activities given the in-country presence of three USAID projects: Supply Chain Management System (SCMS), Systems for Improved Access to Pharmaceuticals and Services (SIAPS) and Capacity *Plus*.

Each of these projects had activities funded by USAID/Washington in support of PtD and a portfolio of activities supported by USAID/Namibia, with the goal of strengthening the supply chain workforce and/or contributing to improved overall HRH/health system functioning. These projects were ideally positioned to carry existing efforts forward and to expand SCM efforts with

¹ People that Deliver focus countries are Burkina Faso, Dominican Republic, Ethiopia, Indonesia, Liberia, Mozambique and Namibia.

limited additional funding. The projects leveraged home and field office personnel to implement this pilot suite of activities and document and disseminate the lessons learned from these interventions.

Human Resource and Supply Chain Management Context in Namibia

Namibia is faced with one of the most severe health workforce shortages in the world. Ranked the third least densely populated country in the world (World Bank 2014)², it depends mainly on expatriate doctors, nurses and pharmacists to fill critical health posts. As an example, in the year 2012, the national ratio of public sector pharmacists per person was 1 to 60,000, with more than 68 percent of those pharmacists being expatriates (MoHSS 2013). The International Pharmaceutical Federation (FIP) notes that in high income countries, the number of pharmacists per 100,000 people ranges from 25 to 250—which is 15 to 150 times the ratio in Namibia (FIP 2012).

With the launch of the medical school and pharmacy degree training programs at the University of Namibia and the Bachelor of Logistics program at the Polytechnic of Namibia's NGCL, the human and institutional capacity in SCM in Namibia has been enhanced over the last three years. These have supplemented the existing nursing and public health training programs at the National Health Training Centre. It is expected that in the medium- to long-term, the Namibian HRH crisis should be improved through these local capacity building efforts and result in less reliance on foreign staff. There are major system barriers in Namibia associated with HRH, according to the Report of the Presidential Commission of Inquiry into the Public Health Sector (MoHSS 2013). For example, the MoHSS experiences high vacancy rates, high levels of attrition and outdated staffing norms that do not accommodate current and emerging health system needs. There is a critical need for training, sustainable salaries and personnel management practices to enhance performance of all health care workers, but the health care supply chain workforce in particular. For SCM workers, the burden intensified with the rapid expansion of HIV/AIDS programming from 2007 to 2012 that increased the quantity of commodities required for prevention, care and treatment almost three-fold (Habimana 2012).

Given the rapid development and expansion of HIV/AIDS services, especially in public and faith-based facilities, the health care workforce required expansion at a rate the government could not support. Therefore, many health care worker salaries were heavily dependent on financing from donors, namely the United States Government through the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund for AIDS, Tuberculosis, and Malaria (Cairney 2014). However, by September 2013, all donor-supported health workers were transitioned to the Government of Namibia payroll and external funding assistance for those positions ended. This followed the reclassification of Namibia by the World Bank in 2011 as an upper-middle-income country, resulting in a decline in the availability of external resources.

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² Based on 2011 Namibian Census

The MoHSS currently manages an integrated health commodity supply chain that serves approximately 350 public health facilities in Namibia, including 35 hospitals, 43 health centers and about 270 clinics (see Figure 1). The CMS in Windhoek is responsible for the quantification, procurement, warehousing and distribution of all pharmaceuticals and clinical supplies, including antiretroviral medicines (ARVs), anti-malarial medicines, TB medicines, HIV rapid test kits, contraceptives and other reproductive health supplies and vaccines. Being the sole procurement agent for all public sector pharmaceuticals and related supplies, CMS handles a significant portion of the public procurement budget. The annual ARV procurement value, which was just under US \$9 million in 2007, increased to just over US \$24 million in 2012. This almost three-fold increase was driven by the rapid expansion of antiretroviral treatment (ART) coverage in Namibia (Habimana, 2012).

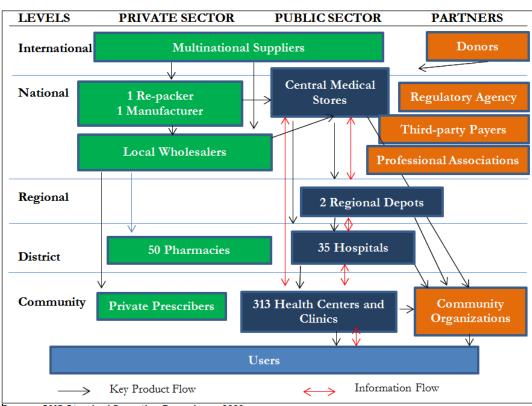


Figure 1: Namibia Health Supply Chain

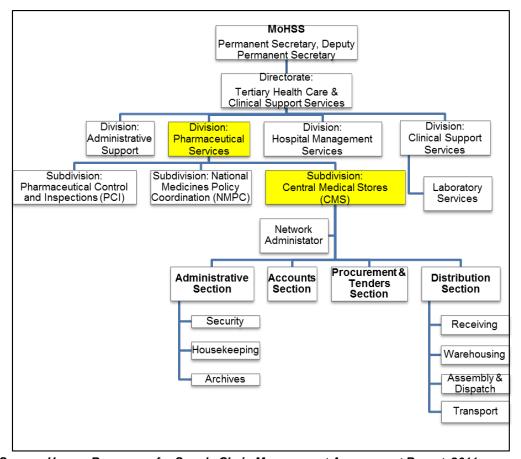
Source: CMS Standard Operating Procedures, 2006

CMS distributes directly to about 45 healthcare facilities on a six-week cycle, including 26 of the 35 district hospitals and the two RMS at Oshakati and Rundu.

Within the public sector, the PtD–Namibia collaboration focuses on the two main players in the public health supply chain: CMS and RMS, which are under the management of the MoHSS Division of Pharmaceutical Services (DPS). CMS is organized into four main operational sections: Distribution, Procurement and Tenders, Accounts and Administrative, and the two Regional Medical Depots have a similar structure, though without a procurement section, as this is done

centrally by CMS. The DPS also manages two other entities with supply chain responsibilities related to medicine selection and quality assurance: the National Medicines Policy Coordination (NMPC) sub-division and the Pharmaceutical Control and Inspections (PCI) sub-division.

Figure 2: CMS Organigram



Source: Human Resources for Supply Chain Management Assessment Report, 2011

Each facility in the supply chain relies on a trained workforce to perform routine activities, including reporting, ordering, storeroom and/or warehouse management and distribution. The frontline supply chain workforce primarily comprises pharmacists and pharmacist assistants, but also includes clerks, nurses and drivers.

Similar to the larger HRH crisis in Namibia, the public health supply chain sector in Namibia faces staff shortages: In 2008, only 27 pharmacists and 65 pharmacist assistants served the approximately 1.7 million clients (85 percent of the population) who utilized public sector health services (O'Hanlon 2008). Likewise, management positions with oversight over supply chain functions are lacking in the MOHSS staffing structure. In a culmination of efforts to expand the professional pharmacist workforce in Namibia, the University of Namibia, supported by the SIAPS program, graduated its inaugural class of 14 students from the new pharmacy program in April 2015. The National Health Training Centre continues to train and graduate approximately 25 pharmacist

assistants each year. Over the long term, these programs will increase the number of locally trained pharmacists and pharmacy assistants.

Objectives and Anticipated Benefits of the PtD-Namibia Collaboration

As the first collaboration of its kind, the pilot of this suite of supply chain workforce strengthening activities aims to build a framework and set of tools to deploy and support a locally trained workforce in Namibia.

The overall objectives of the collaboration are:

- To provide technical assistance to the MoHSS for enhanced planning, deployment, training and retention of the SCM workforce
- To document the implementation process, identify lessons learned and draft a case study/guidance document on strengthening the SCM workforce that can be shared for additional testing and replication in other countries

Successful completion of this work will help achieve the following benefits and results:

- A map of the supply chain workforce at CMS and RMS, with detailed tasks and competencies required for SCM staff
- An estimated recommended number of staff, including the skills mix required for proper supply chain functioning
- Improved supply chain workforce performance, resulting in improved supply chain performance according to a set of identified KPIs

The outcome of this work increases the global value of USAID's contribution to HRH and SCM as well as the PtD Initiative by producing:

- Defined metrics to measure inputs, processes, outputs and outcomes of investments in developing the SCM workforce
- Documentation of the implementation process and lessons learned from this collaboration to inform replication in other settings

The collaboration in Namibia commenced in November 2013 and is expected to be concluded in June 2015, demonstrating an efficient and coordinated response to Namibia's specific HR for SCM needs. The collaboration included four distinct activities, that when combined, created a powerful intervention (see Figure 3), able to develop a supply chain competency framework, identify the number of supply chain personnel required, build capacity in the required competencies and leverage context-specific incentives to encourage staff retention.

Competency Mapping (SCMS) SCPI Program (SCMS) WISN for PH SCM **Rapid Retention/Incentive Study** (CapacityPlus) (CapacityPlus) Partner coordination & documentation of results and lessons learned **Anticipated Results Competency Areas &** Critical numbers of Incentives to encourage job Competency-based Behaviors defined for key required PH SCM staff seeking & retention in the public training provided health supply chain sector are **PH SCM cadres** identified to effectively based on identified identified manage the public skills and knowledge health supply chain gaps Outputs identified competencies Outputs identified facilities Outputs contributed to to include in job descriptions and and cadres requiring salary Activity Standards for in training program and benefits packages WISN Dissemination of results and lessons learned

Figure 3: PtD-Namibia Collaboration Activity and Results Framework

management support from the home office.

These activities are described in more detail in Annex 1 and corresponding technical reports. This technical report focuses only on the implementation and results of the Supply Chain Performance Improvement (SCPI) program as implemented by the SCMS project through its partner IHS, with

II. SCPI Methodology

Introduction to the Supply Chain Performance Improvement Program

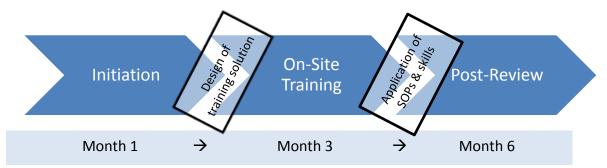
Offsite, in-service training has been the traditional way to build capacity in warehouse management for central and regional medical store staff around the world. Since 2007, IHS (an implementation partner on the SCMS project) has hosted more than 300 warehouse staff from 27 countries at approximately 60 warehouse operations management (WOM) courses in Centurion, South Africa. While it offers a unique opportunity for warehouse staff to visit state-of-the-art warehousing facilities and learn from industry experts, the course is time consuming and expensive. Staff leave their posts for three weeks and pay for travel and lodging, while course tuition is often funded by donor agencies. Furthermore, course participants often are not able to easily apply lessons learned in the state-of-the art facility to their own warehouse environments.

In response to increasing requests for a more country-specific, less resource-intensive WOM course, the warehousing and distribution experts at IHS designed the SCPI program. Focused on the enhancement of public health supply chains and based on ISO-accredited best practices, the program can be adapted to each unique in-country supply chain setting. The program was originally designed to be rolled out in three phases over six months: Initiation, Onsite Training, and Post-Review (refer to Figure 4).

In the Initiation Phase, the program begins by assessing the performance of the current system (a central medical store or another nominated system), identifying and/or establishing baseline metrics (e.g. pick slips per day, volume received/dispatched per day, picking accuracy, stock count accuracy, etc.) and working with the system's owner(s) to set performance metric targets. Additionally in this Initiation Phase a local partner is identified who is able to assist with local accreditation of the SPCI program in line with local legislation. This partner will ensure program sustainability by continuing to meet the capacity building needs of the staff of the identified system.

In the Onsite Training Phase, the SCPI program deploys the tailored training interventions with a focus on staff ability to meet identified KPIs. At the end of the implementation period (approximately six months), the Post-Review Phase occurs and an IHS team evaluates performance improvements against the baseline measures of the originally identified KPIs. In this final phase, the SCPI program materials are also transitioned to the identified local partner. Currently, the SCPI program is accredited by the South African Department of Higher Education and demonstrates incountry ownership through a partnership with The DaVinci Institute, a local South African University that has aligned the training content with the requirements of the Department. In South Africa, the complete SCPI program contributes 30 percent of the credits required for a Bachelor's degree in Logistics. SCPI aims to align itself with other African universities in order to ensure the local availability and sustainability of the program.

Figure 4: SCPI Program Phases & Descriptions



Initiation Phase

- Conduct and/or review existing assessment results, including competency mapping exercises, supply chain assessments, performance evaluations, SO Ps, etc., to understand the system/country context.
- Visit senior management and work together to set performance metric targets and select applicable training modules. Determine program benchmarks based on local legislation, ISO and WHO standards.
- Identify in-country partner(s) to whom to transition the SCPI program.
- Develop an easy-to-follow, step-by-step, customized training solution to help lead and guide the management team in ensuring improvement.

Onsite Training Phase

- In-person, onsite training is performed within the warehouse environment and surroundings.
- Theoretical sessions are completed in a classroom setup, after which participants apply what they learned in a practical setting, under supervision of trainers and managers.
- Training, assistance and guidance instructions are part of the key documentation required by Good Warehousing and Good Distribution Practices (GWP & GDP).
- Key documentation includes the recommended job descriptions/profiles that were identified and created through the competency mapping activity.
- On completion of the course, a full report is compiled, covering practical warehouse activities as well as the contribution of each individual towards the improvement of the system in general.

Post-Review Phase

- A follow-up site visit to review the implementation of methodologies and processes is conducted approximately two months after the training concludes.
- Shared experiences and lessons learned through the SCPI program overall are captured and shared with key stakeholders.
- The SCPI program is transitioned to the identified in-country partner.

Methodology for Piloting the SCPI Program in Namibia

Namibia was the first country to pilot the SCPI program in its entirety. Implementing the SCPI program in Namibia was a natural complement to the Competency Mapping Exercise conducted in January/February 2014 as part of the PtD–Namibia Collaboration. With a full set of competencies identified³ for CMS and RMS pharmacists, pharmacist assistants, clerks and administrative personnel, the SCPI program could be tailored to address those specific competencies outlined for CMS and RMS staff.

The SCPI program in Namibia aimed to enable CMS management to achieve the following:

- Identify non-compliance within warehouse operations and prioritize tasks to promote change in non-compliance areas
- Leverage change management processes to ensure sustainability of the applied changes
- Identify further training/tutoring needs for CMS staff in order to improve capabilities in state-of-the-art warehouse regulations and requirements
- Identify KPIs against which CMS performance could be benchmarked over the course of the SCPI program and beyond

During the initial management meetings to outline the scope of SCPI in Namibia, the SCMS team proposed a few adaptations to the originally designed SCPI program to best suit the local needs and staffing structures. Figure 5 displays the modified five phases, timeline and components of the SCPI Pilot Program and how it was modified for Namibia. Given the ongoing procurement challenges occurring at central level, the SCPI program in Namibia focused primarily on the CMS level and staff to start.

³ See full Technical Report on the PtD-Namibia Competency Mapping Activity – http://www.peoplethatdeliver.org/sites/peoplethatdeliver.org/files/Final%20Competency%20Mapping%20Tech%20 Report PtD%20Namibia PDF%206%2011%202014%20%282%29.pdf

Phase 3 Phase 1 Phase 2 Phase 4 Sobsestills PH SCM **Executive Systems On-Site** Post-**Initiation** Leadership Strength-Review Mgmt. ening **Program** March/April 2014 \rightarrow June 2014 \rightarrow June/July 2014 Nov 2014 May 2015

Figure 5: SCPI Program Pilot Phases Modified for Namibia

Methodology Descriptions by Phase of SCPI

Phase 1: Public Health SCM Executive Leadership Management Program March 31 – April 4, 2014, Pretoria, South Africa

During the program planning discussions with CMS senior management, it became apparent that CMS senior staff required induction training for the SCPI program, as well as a basic leadership and management skills refresher. The purpose was to equip the newly hired CMS managers with essential management and leadership competencies, based on pharmaceutical supply chain principles, for effective stewardship of the SCPI program implementation. This induction training was conducted over five days, from March 31 to April 4, 2014 at the IHS Supply Chain Academy in Pretoria, South Africa. The program included classroom sessions as well as practical, onsite learning at state-of-the-art IHS warehousing facilities (see Annex 2 for a description). In addition, the CMS team visited the Gauteng Medical Supplies Depot (see details in Annex 3), a government-owned, semi-autonomous managed depot, which served as a useful case study for CMS staff: The Gauteng leadership faced similar challenges to those faced by CMS in Namibia, including limited storage space, and effectively addressed the challenges through innovative leadership.

Resources required for Phase 1:

- IHS Executive Leadership Management Program curriculum
- State-of-the-art warehouse and training venue
- Subject matter experts for each of the various warehousing disciplines
- Travel costs and accommodations for five days for each participant
- Minimum of one facilitator to lead the five-day course

Phase 2a: Initiation

June 2 – 6, 2014, Windhoek, Namibia

The goal of the Initiation Phase was to record a baseline for CMS performance and outline the key components of SCPI with the main stakeholders. Two IHS consultants visited Namibia in June 2014 and met with senior CMS management to introduce the SCPI program, communicate objectives and

discuss the step-by-step process, with input from the CMS team. A rough calendar of activities for Phases II and III was also established.

This five-day Initiation in Phase 2 centered on completing the "SCPI Self-Inspection checklist" (see Annex 13) to assess CMS compliance in 251 different supply chain areas. The team completed the checklist through a series of interviews and also an operational site visit to CMS. The consultants then reviewed the audit results and calculated a percentage compliance figure for each area inspected. Scores of 50 percent or below were noted in particular and the consultants identified performance gaps using local legislation, ISO and WHO standards for warehousing as benchmarks for improvement.

The consultants then selected and prioritized activities with the goal of developing training content that would address the identified gaps and ultimately strengthen CMS systems. The consultants presented these recommendations and way forward to CMS management, with an eye toward the next phase: using this content to design curriculum and roll out the onsite training to CMS staff.

Resources required for the Initiation component of Phase 2:

- SCPI Self-Inspection Checklist
- Minimum five days to complete checklist
- Two staff with a good understanding of warehousing best practices to facilitate completion of the checklist
- Buy-in of participants to ensure compliance with the assessment

Phase 2b: Systems Strengthening June 23 – July 4, 2014, Windhoek, Namibia

In the original design, the Initiation Phase would have led directly to development of the training curriculum and delivery of the onsite training. In the context of Namibia after the initial assessments and visit, CMS leadership indicated their desire to rethink some of their systems with CMS before launching into training. In order to facilitate this welcome internal look at systems, IHS consultants adapted the SCPI model to return for a "Systems Strengthening" assignment. Over this two week assignment, the consultants met with CMS management to review a number of systems and procedures critical to ongoing training and capacity building including process flows, standard operating procedures, quality management, and job descriptions. Most importantly, key performance indicators (KPIs) for the overall SCPI program in Namibia were also established in order to gauge what impact the overall SCPI program would have on CMS functions.

The consultants completed the following activities over the two weeks in country:

- Reformatted and updated existing SOPs as well as the development of core SOPs (e.g. Operational, Quality and Health and Safety SOPs). Quality and Health and Safety SOPs were not previously available at CMS.
- Reviewed and redesigned all process flows, including:
 - o Receiving and Acceptance Procedures: Cold Chain

- o Receiving and Acceptance Procedures: General Pharmaceutical and Clinical Supplies
- Receiving and Acceptance Procedures: Security Products and Schedule 4
- o Put away Process
- o Order Capture Procedures
- o Picking Procedures
- Packing and Checking Procedures
- o Dispatch of Customer Order Procedures
- Reformatted and updated job descriptions to include a focus on KPIs and developed job
 descriptions based on Competency Mapping findings to be used when the CMS staffing
 structure is updated.
- Designed Quality Manual and a Health and Safety File, enabling effective quality management of services and products.
- Designed a Site Master File, readying CMS for any inspection.
- Established four KPIs with CMS to track progress of the SCPI initiative overall.

Resources required for Phase 2b: Systems Strengthening:

- Generic SOPs that can be customized to the participating entity
- Subject matter experts for reviewing process flows
- Competency framework to accurately update job descriptions and job description outlines
- Quality Manual and Health and Safety File outlines
- Site Master File outline

Phase 2c: Design of Training Solution October 6 – 17, 2014, Johannesburg, South Africa

The existing SCPI curriculum was redesigned to address identified gaps and to suit the varying competency levels of CMS management and staff while still adhering to warehousing best practices (e.g. ISO, WHO, and GWP/GDP standards). The consultants customized all of the material over two weeks from their South Africa office and consulted with SCMS in-country staff in Namibia as well as staff in Washington, D.C., for additional inputs and quality review.

The content of the training curriculum centered on the key outputs of the Systems Strengthening visit; namely, the need for updated documentation required by GWP and GDP. Therefore, training sessions included content on the updated documentation systems, including:

- New Quality Management System (QMS)
- New Site Master File
- New Warehouse Audit documents
- Revised SOPs

• Updated Occupational Health and Safety Procedures

Resources required for Phase 2c: Design of Training Solution:

- Standard SCPI training curriculum
- Minimum two week timeframe to customize training curriculum
- Two staff with a good understanding of warehousing best practices to customize the curriculum
- Inputs from the local SCMS team to allow adaptation of materials and approach

All sessions were revised and customized to the Namibian context, including standard SCPI curriculum sessions. The content of the two-week curriculum consisted of nine modules covering all SOPs as listed in Table 1. Annex 6 provides a full list of the objectives for each module.

Table 1: Overview of two-week training session curriculum customized for CMS

Topic	Modules	SOPs covered
SOPs	How to write and provide training on an SOP	Applies to all SOPs
Operations	Process Flows	Applies to all SOPs
Operations	Receiving	 Reception of stock Control of stock in Quarantine Control of Non-Conforming of Products Put away of stock
Operations	Cold Chain	Cold Chain
Operations	Picking, Packing and Checking	Picking of OrdersChecking and Packing of Orders
Operations	Dispatch and Distribution	 Dispatch of orders Transportation of orders
Health and Safety	Physical controls, safety and security in the warehouse Good Warehousing and Distribution Practices	 Health and Safety Inspection Sheet Health & Safety Policy Warehouse access & Egress Control Daily cleaning of the Warehouse Incident and Accident Reporting Control of Eating, Smoking, Drinking in the warehouse Rodent and Pest Control
Quality Management	Quality Management	 Recall & Withdrawal of Products Procedure for handling goods reaching expiry dates Effective Stock Rotation Control of counterfeit, Stolen & Damaged Products Roles and Responsibilities Induction Training Storage & distribution of Products Audits and Self Inspection Corrective Action Control of Documents Control of Records Quality management system & management reviews

Phase 3: Onsite Training November 16 – 28, 2014, Windhoek, Namibia

For Phase 3, two IHS consultants, both experienced trainers in warehouse management, conducted a two-week training course for CMS distribution staff (see Annex 6 for a detailed participant list and Annex 7 for the program). The consultants planned to complete this two-week training within the physical warehouse, alternating between theory-based training sessions in a classroom and practical training in a warehouse setting time so participants could apply what they learned under the supervision of trainers, managers and supervisors. Unfortunately, time constraints and availability of training space at CMS limited the scope of the practical, "in-warehouse" application training and physical evaluation. This component could not be fully performed during the two weeks, but was rescheduled to be completed during a follow-up trip. The classroom-based training was completed at an off-site location instead over 9 days.

At the end of the training, the consultants administered a comprehensive evaluation of the participants' comprehension of the theoretical concepts. The consultants compiled the results of the evaluations and shared their thoughts on how the overall implementation of the training went with stakeholders, facility managers and staff. A summary of the findings, together with a recommendation for additional training, is discussed in the "Results" section of this report.

Resources required for Phase 3:

- Two expert trainers in warehouse operations
- Tailored SCPI training curriculum
- Two weeks of time (ideally three), including classroom and in-warehouse training time
- SOPs and process flows to assist the various staff in understanding the implementation guidance

Phase 4: Post-Review

May 4 – 8, 2015, Windhoek, Namibia

Per the SCPI Program design, a follow-up post-review visit should have taken place two to three months after the onsite training. In the case of Namibia, just over five months passed from the time of the onsite training until the Post-Review (Nov 2014 – May 2015) in part due to continued procurement challenges and varying schedules between IHS TA providers, national holidays, etc.. The Review included an assessment of how well staff at CMS implemented the methodologies and processes in which they were trained, as well as re-examination of the SCPI Self-inspection/Audit Checklist and KPIs established in the Initiation Phase. The consultant took three days to complete the assessment to determine SOP implementation, and one day to complete the Self-Inspection Checklist. Interviews and observations were used to complete the SOP implementation checklists (see Annex 8 for a copy). Interviews were conducted with the individuals responsible for the various areas (receiving, warehouse and dispatch) in the distribution area. Observations were performed in all the relevant areas (receiving, warehouse and dispatch) to confirm the interview findings.

The PtD-Namibia team and the IHS consultant shared the results of the Post-Review—including KPI measurements and lessons learned—with stakeholders and CMS senior management to help

inform and guide ongoing implementation of best practice standards at CMS. Recommendations were also given to the Chief Pharmacist on areas that were identified during the Post-Assessment Phase as needing more focus.

Resources required for Phase 4- Post evaluation

- One expert in warehouse operations
- Self-inspection checklist
- SOP implementation assessment checklist
- One week of time

III. SCPI Results

Results from Phase I: Public Health SCM Executive Leadership Management Program

With the purpose of equipping the newly hired CMS managers with essential management and leadership competencies based on pharmaceutical supply chain principles, the five-day Public Health SCM Executive Leadership Management Program was a one-of-a-kind learning opportunity that resulted in changed mindsets and an enthusiasm for the upcoming SCPI program.

The participants

The four attendees—Acting Chief Pharmacist, Procurement Pharmacist, Director of Pharmaceutical Services (which oversees CMS) and SCMS—Namibia Senior Technical Advisor—completed the intense five-day program. The Distribution Pharmacist, a key member of the CMS leadership team, was unable to attend. If funding allowed, the heads of the RMDs would have been an excellent addition. However, having such a small group allowed for in-depth discussion and direct application/comparison of the challenges in Namibia to those in the Gauteng Medical Depot.

Results from Program Sessions

The program featured a number of discussion sessions on a range of pertinent topics and the CMS team compiled their discussion notes to inform an action list for CMS that the Namibian delegation would take back with them to implement. (See Annex 9 for participant list and program summary.)

Table 2: Outcomes for Namibia from the SCM Executive Leadership Program

Program Session Description	Follow-up required by CMS Namibia
Strategic management:	Strategic thinking
Discussion on how to formulate a vision and mission; review of performance indicators such as products and services, organizational values, customer benefits and CMS environment. Discussion on balanced score card strategy map, including tips on how to create a strategy focused organization.	 Create a vision of the long-term nature or profile of CMS Strategic planning Implement process of defining CMS strategy, or direction, and make decisions on allocating resources to pursue this strategy, including capital and people

Program Session Description Follow-up required by CMS Namibia Change management: The team understood the concepts and wanted to apply the following: All aspects of change management were covered including changes required at CMS Namibia: Key drivers and psychology of change What is change management? Managing people who struggle with change Key drivers of change Creating buy-in from the staff for change at **CMS** Why change? Carefully managing resistance to change Psychology of change Recognizing successes achieved Change response cycle Managing people struggling with change Fundamental principles of change Buy-into change management! Tools or components of change management Change management process Five basic principles of change management Change tool insights Coaching and manager training for change management Resistance management Data collection, feedback analysis and corrective action Celebrating and recognizing success Warehouse and quality management The MoHSS team was positive about the concept of quality, acknowledged the importance of it and Introduction to Quality Management Systems, covering committed to implementing the following: topics on Quality Control, Quality Assurance and Quality Audits. Implementing a QMS as soon as it is designed The Warehouse-in-a-Box (WIB) concept and its Implementing Quality SOPs implementation in Tanzania were also reviewed. Performing regular Quality Audits The Warehouse-in-a-Box concept was valuable to the delegation and they will consider it for the two new Regional Medical Stores. Safety, security and risk management Ideas on how to address CMS Namibia's safety and security at all medical stores were shared including: Various aspects of safety, security and risk management were examined, including gate guards, computer Implementing personal searching passwords, time and attendance access control and Using handheld scanners to search staff security cards, as well as protective clothing, reflective Repairing the existing access control gate jackets and hard hats.

Program Session Description	Follow-up required by CMS Namibia
Direct delivery A presentation on direct delivery in South Africa's Public Sector demonstrated how to implement and manage direct shipments of products from manufactures and suppliers to health facilities. In South Africa the top seven suppliers collectively account for 70% of the volume moved to 27 major hospitals across the country. This group was therefore the first tier target in the direct delivery model.	The CMS team was of the opinion that this model can be adopted in Namibia for selected bulk items such as large volume parenteral infusions (vacolitres).
Key performance indicators (KPIs) IHS' bonded warehouse that serves as the SCMS Regional Distribution Centre (RDC) was the focus of the KPI discussion (see Annex 3 for more information on the IHS facility). Measures covering financial, quality, time and productivity were examined.	The following KPIs were discussed in the RDC: Stockout rates Stock turn Staff attendance Quality KPIs Financial KPIs CMS staff are already measuring various operational SOPs.
Communication and Management Communication, time management and team work covered the following: Introduction to communication in management Interactive skills Analyzing interactive styles Process of a typical discussion Key interactive principles CLEAR interactive skills Preparing for difficult interactions Hints on preparing to conduct an interactive discussion	Time management, team work and leadership skills were also highlighted and the importance of implementing the newly acquired skills were understood. The team agreed that regular staff meetings will need to be held to improve communication. Time and attendance of staff will need to be managed to ensure that CMS delivers on their mandate.

Program Session Description	Follow-up required by CMS Namibia
Professional development in a management role Informal discussions were held about the following: • Lifelong learning • Importance of continuous professional development • Taking ownership of your career • Setting development goals	Given their recent appointments, with less than two years on-the-job, and limited prior management experience, members of the CMS leadership team recognized the need and expressed the desire for additional management training and support in their new roles. This request was noted by the Director and will be discussed with the Permanent Secretary.

The overall purpose of exposing CMS management to the "what is possible" was achieved as all members expressed their commitment to implement the follow-up items listed in Table 2, and to continue to bring forward new ideas. Unfortunately, upon their return to Namibia, the managers spent most of their time trying to manage a crisis of shortage of medicines that had been brewing for some time due to delays in execution of procurement plans. Addressing this crisis, which was widely covered in the print media⁴, took precedence over the implementation of their newly identified goals. Though immediate action on these goals was not possible, the participation of the three CMS staff in the Leadership Management Program built support for and buy-in to the overall SCPI program, and created stronger relationships among CMS staff who attended.

⁴ Media reports on shortage of medicines in Namibia:

⁽¹⁾ Health denies blame for shortage:

http://www.namibian.com.na/indexx.php?archive_id=125342&page_type=archive_story_detail&page=1

⁽²⁾ Inexperience and theft caused medicine shortage:

http://www.namibian.com.na/indexx.php?archive_id=125723&page_type=archive_story_detail&page=1

⁽³⁾ Showdown at health ministry:

http://www.namibian.com.na/indexx.php?archive_id=125766&page_type=archive_story_detail&page=1

Results from Phase II: Initiation

As is the case with the implementation of any activity, timing is everything. Unfortunately for the SCPI program, the onsite activities, including baseline assessments and training, all occurred at a time when CMS was in one of the worst procurement challenges it had faced in years. At the time of the Initiation visit in early June 2014, CMS was trying to manage a crisis situation around late deliveries of all essential medicines. Due to delays in execution of tenders for procurement of medicines, CMS experienced some stockouts of essential medicines and clinical supplies, dragging the order fulfilment rate down to below 70 percent.

During this critical time, CMS management efforts focused on expediting the adjudication and award of tenders, including those for much needed ARVs in response to recent changes in ART guidelines. In addition, due to the inadequate transport capacity, CMS fell nearly two weeks behind its published distribution schedule (for deliveries to RMS and district hospitals). Therefore, given the circumstances, and need to ensure product availability for patients, the bulk of CMS distribution staff was focused on picking, packing and dispatching products and not on SCPI activities. CMS management highlighted that the overall timing of the planned SCPI program was not favorable in light of ongoing challenges.

Self-inspection/Audit Checklist Results

After a discussion with the CMS management team, the consultants decided that it was important to continue with the self-inspection to determine the baseline of current activity levels. Together with management, the consultants led CMS through the completion of the 251 item Self-inspection/Audit checklist (refer to Annex 13). The results of the audit found that only 84 of the 251 items were compliant. Figure 6 shows the percentage compliance rates for 24 areas. Each of the 24 areas included from 5–20 sub-areas that were assessed and then averaged together to come up with an overall assessment of compliance for that area.

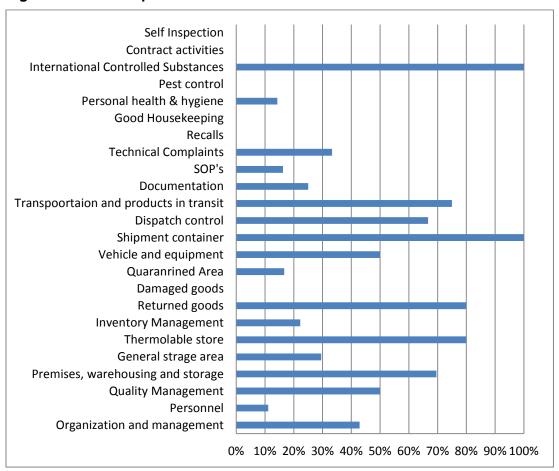


Figure 6: CMS Compliance

Based on this first assessment, CMS was at least 50 percent compliant in 6 of the 25 main warehousing areas. These include:

- International controlled substances
- Dispatch control
- Shipment containers
- Returned goods
- Thermolabile products store
- Premises, warehousing and storage

Note that while over 50 percent compliance was achieved across the sub-areas for each main area, there may still have been some sub-areas with non-compliance. A summary of the baseline compliance in CMS higher-performing areas is listed in Table 3. See Annex 5 for a brief description of each compliance area above 50 percent.

Table 3: CMS Compliance above 50 percent

Compliance Areas above 50%	Compliance Score
International controlled substances	100%
Dispatch control	63%
Shipment containers	100%
Returned goods	80%
Thermolabile store	71%
Premises, warehousing and storage	69%

Of the 25 areas, 18 were at or below 50 percent compliance of all the sub-areas and require immediate attention. Table 4 lists these and Annex 5 describes these in more detail.

Table 4: CMS Compliance at or below 50 percent

Compliance Area at or below 50% Compliance S	
Self-Inspection	0%
Contract Activities (for outsourced services)	0%
Pest Control	0%
Personal Health & Hygiene	14%
Good Housekeeping	0%
Recalls	0%
Technical Complaints	30%
SOPs	10%
Documentation	42%
Vehicles and equipment	50%
Quarantined area	16%
Damaged goods 0%	
Inventory Management 12%	
Quality Management 50%	
Personnel	11%
Organization & Management 30%	
Transportation and products in transit 50%	

The consultant team shared these baseline results with CMS management and together they decided to first focus on strengthening the systems of CMS. Without these systems in place, the capacity building initiatives would have less likelihood of success in making sustainable improvements.

Identifying an SCPI in-country capacity building partner

During this two-week trip, the consultants visited the NGCL at the Polytechnic of Namibia with the goal of discussing the possibility of transitioning the SCPI material to the NGCL (i.e. all the assessment tools, training curriculum and participant evaluations). The consultants met with Professor Chris Savage and Mr. Logan Fransman, who expressed enthusiasm and support for being the local partner to offer the SCPI training to CMS.

Faculty members emphasized that SCPI program/curriculum would have to be registered with the Namibia Qualifications Authority (NQA) as a certificate qualification, to ensure that the certificate is recognized within Namibia. While the registration process can be lengthy, NGCL noted that it would not prohibit it from running the program in the interim through a relationship with the accreditation body in South Africa. Learners attending the interim program would be recognized via "Recognition of Prior Learning" once the program is registered. The team decided that it would be beneficial to the process to ensure that the NGCL is part of the training phase. Mr. Logan Fransman made himself available to attend and assist where possible.

Results for Phase 2: Systems Strengthening

The organizational climate at the time of training has a powerful learning impact that determines the extent to which participants acquire and apply new knowledge and competencies in the workplace.

Given the ongoing procurement challenges and delivery scheduling challenges at CMS, the SCMS team adapted the SCPI program to meet the needs of the client environment. The team proposed to CMS management that the SCPI program should first focus on systems strengthening aspects that would provide much needed management support and make future trainings more effective. This training could start at the end of June 2014, shortly after the first Initiation period visit, and not be dependent on as many CMS staff. CMS agreed to this proposal and postponed the onsite training until after the procurement and distribution challenges subsided.

The focus of the Systems Strengthening visit was to review the documents that support critical CMS management systems. The visit focused on the following key activities:

- Mapping of all process flows in the distribution section of CMS
- Reviewing and updating of Operations, Quality and Health & Safety SOPs
- Reviewing and updating Distribution Section Job Descriptions
- Establishing a Site Master File and Quality Manual
- Agreeing to a set of KPIs on which to assess the progress of the SCPI program

The following subsections describe each of the activities of the System Strengthening visit and key results.

Mapping of all process flows

Process flows are a method of visually documenting the stages involved in performing business procedures. As the existing CMS SOPs were last updated in 2006, the process flows were out-of-date and had limited relevancy for current operations. Consultants identified subject matter experts within CMS to assist with verifying processes for the following four areas in distribution:

- Receiving
 - o Receiving and Acceptance Procedures Cold Chain
 - o Receiving and Acceptance Procedures General Pharmaceutical and Clinical Supplies
 - o Receiving and Acceptance Procedures Security and Schedule 4 Products
- Warehouse
 - o Put-away Process
 - o Picking Procedures
 - o Packing and Checking Procedures
- Customer Engagement
 - o Order Capture Procedures

Dispatch

o Dispatch of Customer Order Procedures

See Annex 10 to review a sample of an updated process flows.

Review and Update of SOPs

A basic SOP framework for a medical warehouse should be centered on three different sections: Quality, Operations and Health and Safety. Boxes 1–3 outline the specific SOPs that the consultants reviewed.

Box 1: Quality Assurance (QA) SOPs

- · Recall & withdrawal of products
- Procedure or handling goods reaching expiry date
- Effective stock rotation
- Control of counterfeit, stolen and damaged products
- Roles and responsibilities
- Induction training
- Storage and distribution of products
- Audits Internal (self-inspection) and External
- Corrective action
- Control of records
- Control of documents and format of SOP
- Quality Management system and management reviews

Box 2: Environmental Health and Safety (SHE) SOPs

- · Health and Safety Policy
- Warehouse access and egress control
- Daily cleaning of the warehouse
- Incident and Accident reporting
- Control of eating, smoking and drinking in the warehouse
- · Rodent and pest control

Box 3: Operational SOPs

- · Receiving & Acceptance of Goods
- Control of stock in quarantine
- Control of non-conforming product
- Put away process
- Order Capture Procedures
- · Picking procedure
- Dispatch of customer order procedures
- Transportation of products
- · Cycle counts and annual inventory

The process started with a meeting held between the SCMS consultants and CMS management. The titles of the SOPs were decided at this meeting. The review of the SOPs was a labor intensive process: it took the consultants one week to review and update the documents. The process started with a review and edits of the existing SOPs, primarily the Operational SOPs, which then were put into the ISO format. Benjamin Ongeri (SCMS Namibia) reviewed these SOPs and then the team submitted them to the Distribution Pharmacist for review and approval. Next, the consultant team started working on the brand new Quality and Health and Safety SOPs that had to be drafted. The Distribution Pharmacist also reviewed and approved these SOPs. A sample of one reviewed SOP can be found in Annex 11.

Review and Update of Job Descriptions

Job descriptions outline what is expected from employees and how they will be evaluated. Job descriptions also assist employers in the appointment of employees and the effective management of roles and responsibilities. The consultant team reviewed existing CMS Job Descriptions for CMS Distribution Section staff, as well as a few other key CMS positions, and found many outdated job descriptions—some belonging to employees that had left CMS. The CMS team decided to redesign the job descriptions for the following positions within CMS:

- Receiving Administrative Officer
- Receiving Pharmacist Assistant
- Warehouse Administrative Officer
- Warehouse Pharmacist Assistant
- Dispatch Administrative Officer
- Dispatch Pharmacist Assistant
- ARV Pharmacist
- Chief Pharmacist
- Distribution Pharmacist
- Pharmacist
- Senior Administrative Officer
- Senior Pharmacist Assistant
- Work Hand

The newly developed job descriptions included KPIs, enabling management to measure the performance of each employee against set standards. In addition to the redesigned job descriptions, the team also developed a set of "recommended" job descriptions that matched the potential positions and job responsibilities recommended from the Competency Mapping activity. Should the Ministry of Health be ready to adopt the recommendations from that activity or others from the PtD–Namibia collaboration, these job descriptions will be ready for immediate applications. The new job descriptions developed included the following:

- Head of CMS (Currently the Chief Pharmacist)
- Operations Manager (Currently the Distribution Pharmacist)
- QA Pharmacist (Currently the Pharmacist)
- Inventory Manager

In addition to updating the current job descriptions for Senior Administrative Officer, Administrative Officer and Work Hand, it was further recommended that the current job titles be renamed to Senior Logistics Officer, Logistics Officer and Logistics Assistant, respectively, to better reflect the nature and importance of the roles. Annex 12 includes an example of a revised job description.

Establishing Site Master File and Quality Manual

A Site Master file is a document prepared by the licensed holder/distributor of medicines as required by the Regulatory Authority of the country in which the organization operates. A Quality File is a set of documents that an organization uses to direct and control the manner in which quality policies are implemented and achieved.

The consultants designed a Site Master File and Quality Manual; however; the following information is outstanding and must be incorporated in order to have a complete file:

- Brief description of CMS and its relation to other sites
- Pharmaceutical activities as licensed or approved by the local Pharmaceutical Regulatory Authorities that may be carried out at the site
- Short description of the site (size, location and immediate environment) and other possible activities on the site as well as details relating to the age of infrastructure
- Aspects of equipment, cleaning, nature of the construction and finishes, ventilation systems (design and efficiency), special areas for toxic, hazardous and sensitive materials, maintenance, qualification and validation programs
- Short description of the QMS, including the Company's Quality Policy, responsibility of Quality Assurance, and management responsibilities, procedures and processes
- Brief description of audit programs and compliance to any standards
- Certificates of approval from regulatory bodies for CMS and responsible personnel
- Code of excellence, stating CMS' commitment to service excellence and assurance of quality products
- Vision, mission and scope of CMS

While the basic framework for the quality and site master file has been developed and some key documents already assembled, there is outstanding information that is required to complete the file, which is central to the CMS quality management system going forward. Some of the information, such as the site layout and licenses, was not readily available. Other information would require additional technical assistance to engage managers in a strategic planning session to define the vision, mission and scope of CMS and develop key policy documents such as a quality policy, code of excellence.

Establishing Key Performance Indicators

The team identified the following four KPIs to measure the performance at baseline and monitor improvements at CMS. The four KPIs identified include:

(1) Percentage of self-inspection checklist items found to be compliant:

Baseline measurement: 84 out of 251(33%) areas inspected were found to be compliant.

The subsequent systems strengthening activities focused on the following areas of the self-inspection checklist in order to improve the score on this KPI:

- Standard Operating Procedures (Training and Implementation)
- Product (Technical) Complaints (SOP)
- Products in quarantine (SOP and activities)
- Damage or rejected goods (SOP and activities)
- Recalls (SOP)
- Good Housekeeping (SOP and activities)
- Pest Control (SOP)
- Procurement and display of basic signage, bin allocation boards and temperature recorders

(2) Percentage of functions completed according to SOPs

Given that all SOPs were reviewed and updated but had otherwise not been updated since 2006, there was no accurate baseline measure taken. The assumption is therefore a 0 baseline.

Improvement will be achieved with SOP (ongoing, regular) training as well as routine monitoring and supervision. The team will need to perform an SOP inspection during the post-intervention visit to determine if SOPs are being implemented and followed.

(3) Order fulfillment rate

This measure refers to the percentage of the quantity of all products ordered by CMS customers that are then supplied from available stock by CMS, commonly referred to as "service level."

- Baseline measure: This KPI is currently measured by CMS and the baseline for the financial year ended March 2014 was 71 percent
- Implementation of SOPs and improved operational effectiveness should lead to an improved order fulfillment rate
- The availability of products directly influences this KPI and it will need to be measured over a longer period than just one quarter

(4) Percentage of customer orders completed according to the delivery schedule

This KPI is currently measured by CMS. The average for the financial year ending March 2014 was 92 percent, but then dropped drastically to just 14 percent during the first quarter of the 2014/15 financial year. This is due to a shortage of products, a lack of SOP implementation and general operational inefficiencies.

- Implementation of SOPs and improved operational effectiveness should lead to an improved percentage of customer orders delivered on time.
- The availability of products could influence this KPI and it should be measured over a longer period than just one quarter.

Overall, CMS greatly supported the work completed in Phase 2, and CMS management accepted all submitted revised and updated documentation. The adoption and use of these documents is the primary focus of Phase 3, Onsite Training. Additionally, the utility of these documents rests in the ability of CMS to implement them and monitor adherence to the outlined procedures and job responsibilities.

Results from Phase 3: Onsite Training

By the time of the training in November 2014, the CMS procurement crisis had still not been fully resolved. Managers struggled to make progress and improve the situation, and this led to confusion, low self-esteem and lack of accountability and motivation among managers and staff members. To enable participants to focus and get away from the stressful work environment, a hotel close to CMS was selected as the venue for the classroom-based training sessions, rather than onsite at CMS. Not only would there be a better chance of learning taking place offsite, it would also ensure maximum staff participation. The hotel environment, while not ideal for practical hands-on application of learning, was the best way to ensure attendance and participation of delegates at that time.

Approach to Training

Before SCPI training could commence, the consultant team knew it was necessary to for managers, supervisors and employees to become aware of the existing problems related to communication and discipline, which emerged during the initiation visit self-inspection and the subsequent follow up systems strengthening visit. The approach used was that the CMS team should acknowledge the problem, talk about it and express the need for change. If the perception that change was not needed remained, the attempt to train and bring about change would fail. The approach would be to facilitate an open and honest discussion around the following issues identified through interactions with staff and management, to understand the causes and contributing factors:

- 1. Poor work attendance of staff
- 2. No adherence to work hours
- 3. Poor communication between staff
- 4. No disciplinary action
- 5. No work ownership

This approach brought about communication and sometimes heated discussions that gave rise to the recognition for the need to change, and participants became willing to adapt behaviors to improve the situation. Yet, this was just the start: the desire to change would need to be sustained through constant motivation over a period of time.

Training: Week 1

In order to conduct the training with minimal interruption to normal operations at CMS, the delegates were divided into four groups. The groups were scheduled to attend classroom training on alternate days. The first four days of training were dedicated to a thorough review and validation of the newly developed QA and SHE SOPs with CMS managers and supervisors. A number of training participants also visited the warehouse of CIC Holdings (a subsidiary of Imperial Logistics) in Windhoek to demonstrate good storage practices and highlight what is possible even in a busy

warehouse environment. Other training participants remained in the warehouse and went through practical training, rearranging and de-junking some of the areas and smaller surrounding warehouses at CMS, focusing mainly on the receiving and dispatch areas.

Training: Week 2

The second week was dedicated to the training of supervisors and workers only. Training on SOPs continued with the focus on warehouse operations and clarification of job descriptions.

By design, the two-week training module included two components, one theoretical and one practical (e.g. working in the warehouse). Due to time constraints and competing priorities, the November training did not adequately cover the practical component. Some delegates attended the theoretical training and job description discussions but did not complete the practical classroom sessions and actual knowledge test.

SOP Training Results

Out of the total CMS staff complement of 60, 50 staff participated in the training and out of these, 40 attended at least 75 percent of the training sessions. Participants were required to complete the training assessment included at the end of each of the revised SOPs to determine their level of competency in the particular activity or task. All these participants successfully completed the assessments and were deemed competent. Workhands were excluded from taking the written competency tests, as some had a limited English language competency. (Refer to Annex 8 for a list of delegates.)

It is important to note that for participants to attain "competency" on the SOP results means that the delegate is competent according to the test results, but this does not necessarily indicate that the delegate is competent in following/implementing the procedures on the job. Some of the SOPs are completely new and the amount of information to absorb might have been overwhelming. Thus, retention of knowledge after initial training may be limited. It is therefore important that continuous training in SOPs become compulsory for all CMS personnel, ensuring new knowledge turns into action and action turns into habit. Follow-up sessions should test employees individually through observation assessments before competency can effectively be determined.

Job Descriptions

Employees need to know what is expected of them, how they will be evaluated and what the consequences will be if they do not adhere to responsibilities outlined in job descriptions. CMS Job Descriptions were revised to describe in detail what is expected from employees and how their performance will be measured through KPIs. A non-conformance form was also introduced that will be completed every time an employee does not fulfill his / her job according to the procedures and job description and will be submitted to the Distribution Pharmacist that will take the necessary action. Consultants utilized a few hours of the training to review each of the following job descriptions and discuss the relationships between different positions, the new responsibilities, and expectations of performance. The following job descriptions were reviewed in the training:

- 1. Administrative Officer: Warehousing
- 2. Administrative Officer: Goods Receiving

- 3. Distribution Pharmacist
- 4. Distribution Workhand
- 5. Pharmacist Assistant: Goods Receiving
- 6. Receiving Pharmacist
- 7. Senior Dispatch Pharmacist Assistant
- 8. Warehousing ARVs Pharmacist
- 9. Administrative Officer: Dispatch
- 10. Pharmacist Assistant: Dispatch
- 11. Senior Administrative Officer: Warehousing

Quality Assurance Forms

The absence of the below quality documents were noticed during the self-inspection that was done during the initiation visit. Management were orientated on how to implement the below Quality documents. These documents will assist CMS to adhere to Good Warehouse and Distribution Practices. The following forms were reviewed in the training:

- 1. Non-Conformance form
- 2. Cold-room and freezers cleaning checklist
- 3. Delivery vehicle checklist
- 4. Forklift checklist
- 5. General warehouse checklist
- 6. Generator checklist
- 7. Health and Safety inspection sheet
- 8. Individual training records
- 9. Internal Audit
- 10. Pallet stacker daily checklist
- 11. Picking error report
- 12. Quarantine label
- 13. Refrigerated item register
- 14. Spill response checklist
- 15. Temperature log
- 16. Training register

Management and Employee Perceived Challenges

On the last day of training, the delegates were requested to write down the challenges they experience when working at CMS. The reason for this activity was to confirm that the consultants correctly identified the staff challenges at CMS, and to place emphasis on the need for change. These discussions confirmed that management and the work force at CMS should communicate better if they want to change. Figure 7 summarizes the perceptions of the delegates:

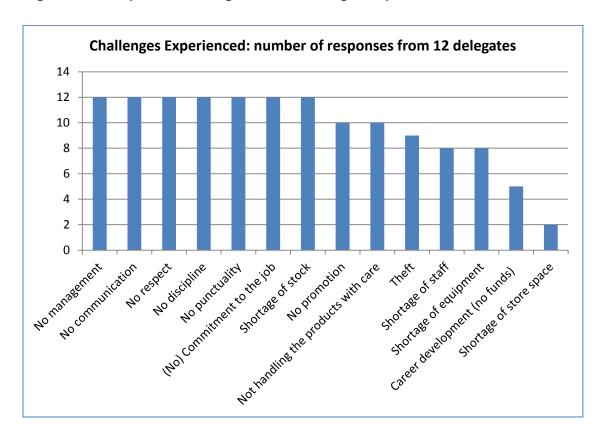


Figure 7: Perceptions of delegates on challenges experienced at CMS

The two weeks training succeeded in ensuring that all attendees understood the importance of the required and designed documentation (i.e. Job Descriptions, SOPs and Site Master File). Unfortunately there was not enough time to ensure that the site master file containing quality management documentation was adopted in CMS and will be reinforced where needed.

Following up on SCPI transition to NGLC

During the Onsite Training visit, consultants took advantage of the opportunity to follow up with NGLC and the accreditation of SCPI in Namibia. Unfortunately, the contract for one of the key contacts at NGCL, Professor Savage, had come to an end in December 2014 and he relocated back to the UK. This, along with the time lapse between the various phases, hampered momentum and enthusiasm for transitioning SCPI to the NGLC. In addition, the South African professional who was to extend the accreditation for the SCPI program to PoN, the DaVinci Institute, also declined the opportunity to work with the NGCL due to DaVinci's constraints in managing quality across international borders. In order to continue moving forward with this initiative, the MoHSS will need to re-engage the NGCL on the registration of the certificate qualification in Namibia. If the NGCL is not interested, then the MoHSS may consider alternative private business schools in Namibia that might be more open to this partnership.

Results from Phase 4: Post-Review

At the conclusion of the Post Review phase, the impact of SCPI was evident not only in the improvement in from the baseline measures of the established key performance indicators, but also in the numerous lessons learned gathered from this initial pilot. In addition to the progress measured by the key performance indicators, the consultants with SCPI program successfully completed the following for CMS:

- Reformatted and updated existing SOPs as well as the development of core SOPs (ie.g..
 Operational, Quality and Health and Safety SOPs). Quality and Health and Safety SOPs
 were not previously available at CMS.
- Reviewed and redesigned of all process flows, including:
 - o Receiving and Acceptance Procedures Cold Chain
 - o Receiving and Acceptance Procedures General Pharmaceutical and Clinical Supplies
 - Receiving and Acceptance Procedures Security Products and Schedule 4
 - o Put away Process
 - o Order Capture Procedures
 - o Picking Procedures
 - o Packing and Checking Procedures
 - o Dispatch of Customer Order Procedures
- Reformatted and updated job descriptions to include a focus on KPIs and developed future job descriptions based on Competency Mapping findings, to be used when CMS staffing structure is updated.
- Designed Quality Manual and Health and Safety File, enabling effective quality management of services and products.
- Designed a Site Master File, readying CMS for any inspection.
- Customized a two-week onsite training curriculum (Annex 7 includes a detailed outline of the two-week curriculum, including session objectives).

Progress against Key Performance Indicators

Percentage of self-inspection checklist items found to be compliant

The SCPI program facilitated a 39% increase in compliance. During the initiation phase, 84 out of 251 areas inspected (33 percent) were found to be compliant; however, by the completion of SCPI, compliant areas increased to 180 out of 251 areas inspected (72 percent). (See Annex 13 for a detailed list of those checklist items found to be compliant.)

Percentage of functions completed according to SOPs

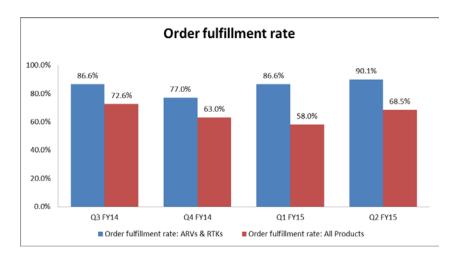
This KPI was not originally measured at the baseline, as the SOPs were not fully implemented or documented at CMS. SCPI required a comprehensive review and update of all SOPs for the distribution section. During the Post-Review phase, a consultant conducted interviews with the individuals responsible for the various areas (receiving, warehouse and dispatch) in the distribution area, and through observation confirmed the interview findings to complete the SOP implementation checklists. On the completion of this intervention, CMS SOP compliance rates ranked at the following percentages:

- Operational SOPs: 96 percent
- Quality SOPs: 55 percent (these were newly developed SOPs for CMS)
- Health and Safety SOPs: 42 percent (these were newly developed SOPs for CMS)

Order fulfillment rate

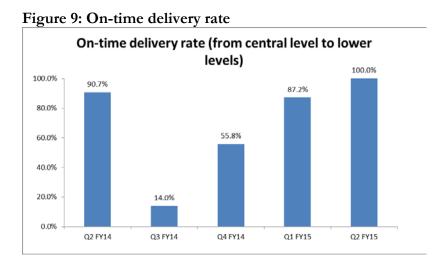
From the initial baseline measurement at the start of the SCPI Program, CMS order fulfillment rates for ARVs were at an all-time low of 77 percent in Q4 of FY14, but gradually increased to prior levels of over 90 percent in Q2 of FY15 during the post-review (see Figure 8). The order fulfillment rates (also known as service levels) for other essential medicines, however, did not rise above the "acceptable" level of 80 percent over the entire year. While the ARV fulfillment rate increased, SCPI likely did not have an impact on either ARV or other product fulfillment rates, as the underlying cause of the lower rates was related to the absence of long-term contracts with suppliers. This absence resulted in multiple requests for quotations and long order replenishment cycle times—two areas in which the SCPI training program did not focus, but which presented great challenge for CMS throughout the entire implementation of SCPI.





On-time delivery rate from central to lower level

From an all-time low of 14 percent in the third quarter of 2014, CMS on-time delivery for orders to health facilities improved remarkably, to 100 percent (See Figure 9). This was the result of multiple factors, including the SCPI program. Additionally, CMS recruited new drivers, workhands and pharmacists, and also instituted weekly distribution staff meetings. As a result of the 2014 procurement crisis, the Deputy Permanent Secretary attended the weekly CMS management meetings. Increased capacity building, coupled with active management and oversight, surely contributed to the rise in on-time delivery rates.



The PtD-Namibia team and the IHS consultants shared the results of the Post-Review, including KPI measurements and lessons learned, with stakeholders and CMS senior management to help direct on-going and future implementation of best practice standards at CMS. Recommendations were also given to the Chief Pharmacist on areas identified during the Post-Review Phase that required more focus. See the following "Recommendations and Lessons Learned" Chapter for additional information.

IV. Recommendations and Lessons Learned

Over the course of four different phases in just over twelve months, the SCPI program gained extensive insight into the operation of the Namibia CMS, particularly the distribution section, and made significant strides in building the capacity of the CMS supply chain workforce. This first-ever pilot of phased performance improvement spanned a wide range of concepts and activities, from executive leadership engagement and SOP development to interactive, competency-based training activities. The results were overwhelming and the return on investment clear.

Recommendations

It is recommended that several issues be addressed by management, both at CMS and within the higher levels of the MoHSS. These include the following:

Elevate CMS to become a Directorate under the MoHSS. This strategic move will allow CMS to gain some autonomy and flexibility to adopt best practice activities and behaviors. This will also elevate SCM issues to the senior management level, enabling more effective advocacy for resources and resolution of supply chain bottlenecks, such as those currently plaguing the procurement of medicines. With this elevation, it is expected that human resources performance management will be accorded greater attention with dedicated staff to coordinate staff recruitment, deployment, on-boarding and performance appraisal, including disciplinary matters and separation, and retention and performance incentives.

Review the staff structure to establish posts for some critical areas of responsibility. The following recommended positions are required at CMS to ensure a well-functioning central medical store and to promote accountability (draft job descriptions for these positions have already been designed):

- Head of CMS (Director): Provides overall strategic direction for CMS while the Chief Pharmacist takes the role of the Responsible Pharmacist
- Inventory Manager: Focuses on monitoring the inventory across the entire supply chain, forecasting future requirements and supply planning
- Quality Assurance Pharmacist: Assumes responsibility for the QMS, including undertaking self-audits and instigating corrective actions

Implement continuous professional development and mentorship for CMS management and staff. It is important that the current management of CMS receive support to ensure that they will be successful in carrying out their required functions. This support includes leadership and management development and a dedicated mentor to help ensure introduce and/or reinforce the required management skills and self-confidence in a timely fashion. Additionally, CMS staff would

benefit from more regular monitoring and supervision of their performance and opportunities for professional advancement.

Maintain weekly staff meetings. It is extremely important that the management of CMS engage with its work force regularly. This will ensure that CMS management and team members can openly discuss and learn about successes and challenges in their work environment.

Hold compulsory SOP refresher training annually for CMS; extend to RMS. SOPs need to be reviewed annually and staff trained to ensure that all CMS staff members are informed of any changes or updates to SOPs, and so that any new staff can gain the appropriate skills and implement SOPs effectively. More frequent (monthly and on a rotational basis) SOP training that take a hands-on approach will ensure that the correct procedures are followed and that quality standards are maintained within CMS. Regular SOP trainings will also need to be extended to RMS. SOPs will need to be revised for RMDs and SOP training also extended to RMD staff.

Continue engagement with local training institutions to offer SCPI certification. Given the already established logistics and supply chain training capacity at the PoN, it is recommended that MoHSS pursue a memorandum of understanding with the NGCL to clarify the way forward for the SCPI. Alternatively, the MoHSS may consider engaging with other local private academic institutions, as these may have a more flexible decision-making structure in terms of the introduction of new courses and may be able to pursue the accreditation of the course materials with the NQA. Having a local SCPI training partner will provide the MoHSS with a sustainable solution for capacity building in SCM of health commodities.

Lessons Learned

Central to the success of any SCPI program is continuous local buy-in and stewardship of the SCPI initiative at all phases. The SCPI program is by nature designed to facilitate an organizational shift in thinking. The change management process requires both senior management and front line management buy-in and stewardship that must be sustained throughout the phases of the program. The executive leadership program created the awareness for change and buy-in among senior CMS management and was a valuable addition to the SCPI program.

A flexible structure allows for a more tailored performance improvement solution. The SCPI framework provides a state-of-the art, flexible structure that can be adapted to a variety of existing circumstances affecting a CMS or RMS. For example, in the original design, the Initiation Phase would have led directly to development of the training curriculum and delivery of the onsite training. In the context of Namibia, after the initial assessments and visit, CMS leadership indicated their desire to rethink some of their systems before launching into training.

In order to facilitate this welcome internal look at systems, IHS consultants adapted the SCPI model to include a "Systems Strengthening" assignment to review a number of systems and procedures critical to ongoing training and capacity building including process flows, SOPs, quality management and job descriptions. The training curriculum was then updated to reflect this new focus; namely, the need for updated documentation required by Good Warehousing Practices (GWP) and Good Distribution Practices (GDP), including a new Quality Management System, Site Master File, new

Warehouse Audit documents, revised SOPs, and updated Occupational Health and Safety Procedures.

A pre-SCPI assessment may help in planning and budgeting. While the SCPI program was flexible and adaptable, any changes, such as adding a systems strengthening component, are likely to significantly impact the scope and timelines, and subsequently, the program budget. A pre-SCPI assessment may be necessary to thoroughly review the local client environment and systems before designing the adaptation and budget for the actual SCPI activity.

Overall staff morale will affect the effectiveness of the SCPI program. Management buy-in for change is important, but staff buy-in and morale is equally important. At the onset of the training, it was clear that the staff morale was low. Facilitators ensured that issues were discussed openly between management and staff, and recommendations were made incorporating input from all sides. Staff would not have been open to change if the benefits of the change were not communicated clearly.

The existing organizational structure of CMS affects the change management process. The organizational and management structure of a given CMS is unique to its respective country. There is a varying level of autonomy of each CMS, and a range in the kind of control that managers can exercise over certain functions such as procurement and resources including staff deployment, training and performance management. To achieve sustainable institutional change and performance improvement, where CMS is embedded within the Ministry of Health and under the civil service structure as in Namibia, requires coordinated involvement and support of a multiplicity of actors, some of who are outside CMS or the Ministry of Health. This level of coordination is not always possible to achieve and may therefore affect the results of the program.

Practical application and evaluation is critical to a comprehensive training program. While the classroom-based training was completed and beneficial to staff, due to the ongoing procurement crisis and delivery delays, the onsite training component of Phase 3 was not entirely completed. While classroom learning was beneficial, the on-the-job application of newly gained skills is extremely important and would ensure that the new skills are ingrained into participants' understanding and are monitored continuously over time by management.

In-country certification of the SCPI is important and can be challenging. The in-country certification of the SCPI provides local credibility to the program. Currently, the SCPI program is accredited by the South African Department of Higher Education and demonstrates in-country ownership through a partnership with a local South African University that has aligned the training content with the requirements of the Department. In South Africa, the complete SCPI program contributes 30 percent of the credits required for a Bachelor's degree in Logistics. SCPI aims to align itself with other African universities in order to ensure the local availability and sustainability of the program.

Efforts to accredit the SCPI with the Namibian German Centre for Logistics (NGCL) at the Polytechnic of Namibia (PoN) were not immediately successful due to changes in leadership at the NGCL. There was also some reluctance by the PoN to invest in accreditation of the course with the Namibia Qualifications Authority (NQA) without being assured of the demand for the course

through a commitment from the MoHSS. A key lesson learned here is that in-country certification is a lengthy process requiring technical support to the targeted institution to build a business case that will justify the investment needed to introduce and accredit a new course.

Annexes

ANNEX 1: PtD – Namibia Collaboration Activity Summary

*As written in the January 2014 Summary Document.

Activity 1: Health Supply Chain Competency Mapping Exercise

PtD recently released its Health Supply Chain Competency Compendium reference document, outlining the domains and competencies required for the workforce at different levels of the supply chain. The compendium draws on 20 competency frameworks and related documents from a number of organizations globally. SCMS will lead the application of the PtD competency compendium to help the Namibian MoHSS and CMS identify:

- SCM tasks required at CMS and RMS
- Competencies required to complete tasks
- Employees currently completing tasks.
- Gaps, redundancies, recruitment and training needs

The competency mapping exercise is activity and evidence based rather than focused on individual jobs. It has been reviewed against current best practice in the available literature. A comprehensive competency framework requires country-specific input to outline all the relevant competencies. This can be achieved through six iterative steps that include:

- A desk audit of key SCM workforce resources (i.e., job descriptions, SOPs, policies) to produce a cursory map of supply chain competencies by cadre, highlighting gaps and overlap.
- A stakeholder engagement workshop to introduce the activity to key partners and validate the initial desk audit findings.
- In-country interviews and focus groups to outline SCM activity process maps, which highlight responsibilities of each cadre.
- Comparison and compilation of desk audit and process map results into draft competency frameworks by cadre.
- Key informant validation of draft competency frameworks.
- Presentation of results to high-level stakeholders to agree on next steps for application of the competency framework(s).

The end result will be a competency framework for specific supply chain teams, which in Namibia's case includes pharmacists, pharmacist assistants and clerks. Once the team-specific competency frameworks have been created, it can be used to:

- Guide the design of training and curricula, performance frameworks, and job descriptions for different teams of health workers.
- Identify gaps in services (including accurate implementation of the WISN tool see description under Activity 2).

Activity 2: Workload Indicator of Staffing Need (WISN) Tool

One step to improving the accessibility and quality of health care is to establish what numbers and types of health workers are needed to match the volume of services in particular facilities. In Namibia, where staffing norms had not been revised in more than 10 years, Capacity *Plus* is assisting the MoHSS in using the Workload Indicators of Staffing Need (WISN) tool to estimate workload requirements for doctors, nurses and pharmacists in all 13 regions of the country.

Developed by WHO, WISN supports data-based decision making in workforce planning and management by calculating the number and types of staff a health facility should need based on actual workload. Users of the tool define the components of the workload for the particular type of staff; set the time it takes a trained, well-motivated worker to perform components to acceptable professional standards; determine the time a health worker has available in one year to do his or her work, taking into account absences (such as leave days); and identify available workload data. These staffing standards and service statistics are then entered into the WISN software for analysis.

The WISN application in Namibia revealed staff shortages — especially among medical officers and pharmacists — and inequities in staffing, particularly between health centers and clinics. Some clinics offer the same amount of care as large health centers, yet they may have only one or two nurses according to current staffing norms (as opposed to the national average of 9 nurses per health center). In addition, workload can vary widely at the same type of facility. For example, in the case of two clinics, each staffed with one registered and one enrolled nurse, data revealed that one clinic had seen 13,541 outpatients in a year while the other had only seen 1,867.

WISN results have informed numerous policy recommendations that will now be considered by the MoHSS' restructuring committee to help address shortages and imbalances of staff in facilities. The same approach can be used to estimate the country's need for staff with supply chain management functions. The WISN method is based on a position's workload, with activity (time) standards applied for each workload component. The method:

- Determines how many workers of a particular type are required to cope with the workload of a given facility.
- Assesses the workload burden of that facility's staff.
- Estimates the staff mix required to deliver expected services based on workload.
- Establishes fair workload distribution among staff.

Activity 3: Supply Chain Performance Improvement Program (SCPI)

SCMS — through one of its partners, IHS — offers an in-country SCPI program, designed by specialists with in-depth field experience in warehousing and distribution. The program is focused on enhancing public health supply chains, based on ISO-accredited best practice, and is designed for unique in-country supply chain settings. The program has been structured to complement the outputs of assessment tools, such as WISN, and other programs, such as workload assessments.

The SCPI begins by assessing system performance of a defined level of the supply chain and assists with identifying and/or establishing baseline metrics (pick slips per day, volume received/dispatched per day, picking accuracy, stock count accuracy, etc.), working with the system owner(s) to set targeted performance by metric. The training solution is then designed, taking into consideration the results of the competency mapping and WISN exercises. The SCPI will then deploy the necessary training interventions and measure their impact by the improvement of performance metrics and staff over time.

The current SCPI program is accredited by the South African Department of Higher Education, and the complete program contributes 30 percent toward a bachelor's degree in Supply Chain, registered in South Africa. With in-country ownership and sustainability in mind, SCPI looks to with the Polytechnic of Namibia as well.

SCPI Progr	SCPI Program Outline	
Initiation	 A visit to work with senior management to set performance metric targets and then select applicable training modules. Local legislation and ISO and WHO standards are used to determine the benchmark for the training. Provides an easy-to-follow step-by-step program that will guide the management team to guaranteed improvement. 	
Onsite Training	 The physical training is performed onsite within the warehouse surroundings and infrastructure. Theoretical sessions are done in a classroom setting, after which the delegates will implement practically what they have learned under the supervision of trainers, managers and supervisors. Training and assistance is given in compiling key documentation required by good warehousing practices (GWP) and good distribution practices (GDP). On completion of the course, a full report is developed of practical work done in the warehouse and how individual performance will contribute to improving the overall system. 	
Post Review	 A follow-up site visit is conducted two months after the training to review the implementation of approaches and processes. Shared experiences and lessons learned through the training program are captured and shared with key stakeholders. 	

Activity 4: Discrete Choice Experiment (DCE)

Capacity *Plus* is working with the MoHSS to apply the Discrete Choice Experiment (DCE) methodology to determine attraction and retention factors for various cadres of health staff, including pharmacists and pharmacy assistants. The Discrete Choice Analysis (DCE) is a quantitative research method that measure the strength of preference and trade-offs of the health workers towards different job characteristics that can influence their decision to take up rural postings (WHO, 2012). This approach is useful to better understand which economic and non-economic incentives are necessary in order to attract health workers to work in the public sector in rural areas and address the urban/rural misdistribution of human resources for health. It is a robust methodology which uses the choice-based conjoint analysis to test the impact of any proposed actions or strategies. (Huber, 2005) (Mengoni, Alessandro, Seghieri, Chiara, Nuti, 2013).

The DCE has two components, the use of discrete choice analysis to model preferences from data gathered through focus group discussions and the use of experiments, and the DCE questionnaire, to generate the required data, eliciting stated preferences for products of programs (Viney et al., 2002). The approach will use logistical regression analysis to establish preferences that respondents have between different job attributes. The outcome of the logistical regression model would establish a preference calculation, the Preference Impact Measure. This measure would be indicated as "willingness to pay" and would be used to compare the "utility coefficients" of each job characteristic in terms of flexibility of the salary coefficient and it would be used to offset an increase in one job characteristic towards other and thereby influences preferences for health workers to choose urban job postings as opposed to rural job postings. The Preference Impact Measure which would identify, for instance, how much salary a respondent would be willing to forgo in order to obtain other benefits or incentives. In short, it would be used to measure the impacts of an improvement of one of six job characteristics to the appetite for respondents to choose a job posting in a rural area as opposed to a job posting in an urban area.

The envisioned impact would be to design incentive systems and retention strategies to attract and retain health professionals and scarce skills to remote/rural and hardship areas in the public sector. The overall impact on the public health sector would be better service delivery to populations since the current shortage of health workers would have been relieved, especially in rural and hardship areas. In December 2013, Capacity *Plus* conducted a hands-on training on the methodology with MoHSS counterparts which covered the DCE concept, process and application of results followed by a pilot survey administered to pharmacists and pharmacy students to determine factors that motivate them to work in district hospitals. The full survey is expected to be implemented in the third quarter of FY14 after revision of the survey tool based on the pilot.

ANNEX 2: Public Health SCM Executive Leadership & Management Program

Participants

Names	Designation
Mr Lazarus Indongo	Deputy Director Pharmaceutical Services Namibia
Mr Tonata Ngulu	Acting Chief Pharmacist Namibia.
Ms Seija Nakamhela	Procurement Pharmacist Namibia.
Mr Benjamin Ongeri	Snr. Technical Manager SCMS.

Program

	Day 1		
09:00-09:15	Opening and welcoming		
09:15-11:15	Facility walk about (HIS Warehouse and premises)		
11:15-11:30	Tea		
11:30-13:00	Professionalising the Supply Chain		
13:00-14:00	Lunch		
14:00-15:00	Challenges in warehousing and management		
15:00-16:00	Management and supervision		
	Day 2		
09:00-10:30	Contract level agreements and management		
10:30-12:00	Change management		
10:30-10:45	Tea		
12:00-13:00	Good Warehousing and Distribution Practices and		
	Management		
13:00-14:00	Lunch		
14:00-16:00	Communication and management		
00.00.11.00	Day 3		
09:00-11:00	Safety and security in the warehouse and management		
10:30-10:45	Tea		
11:00-13:00	Strategic Planning		
13:00-14:00	Lunch		
14:00-16:00	Strategic Planning Pay 4		
09:00-11:00	Day 4 Warehouse daily KPIs and management thereof		
11:00-13:00	Team management		
13:00-14:00	Lunch		
14:00-16:00	Gauteng Medical Stores Visit		
14.00-10.00	Day 5		
09:00-11:00	Time management		
11:00-11:15	Tea		
11:15-13:00	Decision making and management		
13:00-14:00	Lunch		
14:00-16:00	Leadership skills		
1 10.00	r		

ANNEX 3: Imperial Health Sciences Warehouse Facility

The IHS facility employs 400 people and serves a total of 38 clients (mainly pharmaceutical companies). Outsourced services such as security, cleaning and outbound freight account for an additional 350 staff on premises. The facility has a strict security policy that entails all visitors into the warehouse to be screened and to declare any medicines in possession prior to entry. Cellphones are not allowed in the warehouse and employees have to surrender phones at entry point.

There is a complete and consciously labeled chemical spill kit near the entrance to the warehouse with the names and contacts of the Hazmat response team on display above the kit. All notice boards display the organogram of the organization as well as key provisions of the Labour Act and the Occupational Health and Safety Act.

The warehouse uses SAP ERP for all business processes which include an automated WMS system complete with Psion Teklogix Workabout Pro handheld computers / scanners for put-away and picking of items. The warehouses have a ceiling height of 10m with 5 levels of adjustable pallet racking each with a maximum load capacity of 2.5 tons.

All pallets are weighed prior to placement on racks. All cartons are weighed and the weight per unit is used to validate the quantities at the point of checking prior to dispatch. Euro pallets of dimension 800 x 1200mm are used throughout the warehouse with each rack level holding 3 pallets. The distributing warehouse has quick pick shelving consisting of gravity flow racking and narrow isles racking.

All inbound shipments must be booked in advance and receiving shipments are done strictly according to allocated delivery times/schedules. A typical day/shift at the warehouse facility starts with staff meetings at each section where staff share important issues and feedback from the previous day/shift and get updates from supervisors. KPIs are tracked continuously and used to reward staff whose performance excels with an "employee of the month" incentive. The KPIs commonly used are:

- Line per picker man-hours;
- Number of line picked;
- Number of picking errors reported during checking;
- Staff attendance percentage;
- Number of incomplete replenishments; and
- Inventory location accuracy.

ANNEX 4: Gauteng Medical Supplies Depot

The Gauteng Medical Supplies Depot, a government owned, semi-automated and managed depot, as originally an abattoir before it was converted into a medical supplies depot about 40 years ago. The facility faces the challenge of limited storage space with low ceilings that can only accommodate 2 levels of adjustable pallet racking.

The depot has an arrangement with the Gauteng provincial government to levy a logistics fee through charging a mark-up of 5% on the exit price of all medicines and supplies distributed by the depot. The logistics fee is used to cover the operational costs of the warehouse as well as payment for new commodities, salaries and outsourcing of transportation and cleaning services.

The depot has a total of 100 full time staff including 19 pharmacists and 32 pharmacists' assistants. The roles of pharmacists are:

- 1 Director of Pharmaceuticals overall Manager;
- 4 Quality Control Pharmacists in the in-house QC laboratory;
- 2 Warehouse Managers Inbound and Outbound;
- 2 Pharmacists for Schedule 6 items at Receiving and Dispatch; and
- 10 Pharmacists working in the Procurement and Contracts section.

All pharmaceutical products received are kept in quarantine and each batch is sent to the in-house QC laboratory for testing before the goods are moved into the warehouse. The laboratory has a turnaround time of 1 to 2 days. Short-dated items received (less than 1-year remaining shelf life) are accepted only on condition that the supplier provides a letter agreeing to the return of the products if not used before the expiry date.

The facility has a computerized stock management system but no warehouse management system. Put-away and picking is therefore done manually in the same way as at CMS Windhoek. The depot delivers stock to a total of 120 facilities once a week with large facilities being served up to twice weekly. The furthest delivery point is only 2 hours away.

Hospitals utilise a remote demander's module within a Virtual Private Network for ordering stock, allowing the depot to see the order as it is placed and initiate the dispatch process immediately. The depot (same as CMS Windhoek) does not review and restrict the quantities ordered by health facilities unless it appears to be an obvious error in the order quantity. The depot maintains approximately 3-months stock-holding. Emergency orders are restricted to no more than 5 items while health facilities must arrange their own transport to collect such orders.

Orders for items that are out of stock at the depot remains on "back order" or "due out list" and are only filled as products becomes available. The system only allows one back order per facility. Cycle stock counts are conducted regularly by "Verification Officers", counting 5 to 10 items daily.

Stock discrepancies are investigated and resolved. Health facilities are given up to 2 days to inform the depot of any discrepancies in the type and quantity of products supplied and invoiced. Stock taking is done bi-annually (in September and March) and the stock accuracy rate is normally around 95%. Stock pilferage was common until the depot introduced strict access control protocols and cage-like lockable trolleys that are secured with two tamper-evident seals and loaded into trucks for transport of products all the way to health facilities. These cage-like trolleys called "Rolltainers" are described as "pilferage resistant units" and have lockable / sealable gates and thick walled tube cladded with fine grade expanded metal or weld-wire mesh that provides added security. They are ideal for the picking / packing processes in warehouses and distribution to stores across the country. All units are collapsible and can be stacked away, allowing space saving and optimized returnable logistics.

The depot has a total of 256 CCTV cameras and the system stores up to 3 months of footage. A biometric (finger-print) access control system is used for keeping time and attendance records, assisting human resource management. Seals numbers for key/security items are featured on dispatch forms and verified at facility level before cages are opened. Disposal of expired and damaged medicines is outsourced. The service company collects the unusable stock on a monthly basis for destruction. The responsible pharmacists in both organizations are involved in the transfer of custody for disposal of schedule 5 & 6 (narcotics and psychotropic) medicines.

The depot is partitioned into several stores used to store specific dosage forms or product groups (e.g. ARVs, liquids, syrups). Within each stores, each row of racking has the names of designated shelf marshals who are responsible to ensure that products on racking are stored according to good storage practices.

Although being very old, the facility is managed very well owing to:

- Very tight controls;
- Strict implemented policies; and
- Continuous staff training.

ANNEX 5: Initiation Visit Self-Inspection Checklist Results

A. Area with Compliance Above 50%

& Score International	International controlled substances are kept at the facility and they are
International	International controlled substances are kept at the facility and they are
controlled substances	stored in compliance with International Conventions and National
(100% compliance)	Legislation, Regulations on Narcotic Drugs. There is an up-to-date register of all International Controlled medicines purchases and sales, which records: • The name and business address of the supplier • The name and business address of the purchaser
	 The date of each such transaction The quantities recorded or sold
	 The balance held in stock at the end of each year The records are kept for at least 5 years after the last date of sale and all psychotropic medicines are stored in a restricted area and narcotic medicines are locked away and the keys are under the control of the Distribution Pharmacist.
Dispatch control (63% compliance)	There is a written SOP relating to the control of goods dispatched to the clients but the dispatch bays do not protect deliveries from bad weather during loading. Current lists of approved and valid customers are available but not regularly updated. Records for the dispatch are prepared and include the following information: Unique number to allow identification of the delivery order? Date of dispatch Name and address of suppliers Name and address of addressee A description of the products Assigned batch number and expiry date Applicable transport and storage conditions
	Vehicles and containers appear to be loaded carefully and systematically on a first out/last-in basis in order to save time when unloading and to prevent physical damage. Packaging material are used adequately to protect goods whilst in transit, but no suitable procedures were in place to clean up spillages in the transport vehicle as soon as possible to prevent possible contamination and cross contamination. The designated personnel of the Distribution section has not been trained

Shipment containers (100% compliance)	in "cold chain management" of the transport of thermolabile products but suitable procedures are used to maintain the cold chain (i.e. suitable coolants, insulation material) Thermolabile products are adequately protected from being compromised and includes the wrapping of probes in bubble packs and isolated from freezer blocks) Written procedures are not in place to investigate and deal with any "cold chain failure" and no "cold chain variance form" is available or completed. Thermolabile products are dispatched in cold chain containers and special care is taken when using freezer packs to ensure that the pharmaceutical product does not come into contact with the freezer pack. All pharmaceutical products are stored and distributed in containers which do
	not have an adverse effect on the quality of the products, and which offer adequate protection from external influences, including microbial contamination. Labels are applied to the majority of containers and are clear, permanently fixed to the container and indelible. Information on the label complies with applicable national legislation and special transport
	and/or storage conditions are stated on the label.
Returned goods (80% compliance)	There is a written SOP available for the handling of returned goods, but has not been updated for the past 8 years. All the examination, assessment and
	decisions regarding the integrity of the returned goods are channeled through the Distribution Pharmacist and returned goods are immediately separated from saleable/useable stock until their final disposal. Batch-specific records are only kept for ARV's and not on all goods returned. The Distribution Pharmacist formally release goods for return to stock.
Thermolabile store (71% compliance)	Thermolabile medicines are stored in a fridge/cold room and only medicines are stored in the fridge/cold room. Thermolabile medicines are also stored according to a document driven system but no SOP is available. All consignments of vaccines are checked on receipt and transferred to the fridge/cold room immediately. The Pharmacist at receiving does check the temperature monitor indicator within the cooler box to ascertain whether the delivery was maintained and received within the prescribed requirements of 2°C - 8°C but no Cold Chain Maintenance log is available. The fridge/cold room in working order and maintained regularly but no maintenance log was available for the fridge. Temperatures are also monitored in the fridge/cold room with temperature recorders, temperature are recorded daily but no proof was available that the devices are calibrated regularly. An adequate warning system is in place to indicate power, fridge or cold room failure, this is done via an automated sms system. CMS has a back-up generator in place for the fridge/cold room and it is tested quarterly. No SOP or documented procedures are in place for maintaining the cold

chain in the event of fridge failure, vaccines are also not quarantined after a "cold chain failure" and no "cold chain variance form" is available for completion. Temperature recorders/maximum-minimum thermometers in the fridges/cold room and cool boxes are also not calibrated at defined intervals.

Premises, warehousing and storage (69% compliance)

Access to the Receiving Department is not secure and restricted to authorized persons only and deliveries are not protected from bad weather during unloading. The receiving bay is one huge open area that is not effectively separated and clearly defined. The area is also not designed and equipped to allow the cleaning of containers of incoming goods, if necessary, before storage. A receiving team is available during receiving at all times and consists out of a Pharmacist assistant, Clerk, work hands and a Pharmacist if required. A security guard would be a welcome addition to the team. Staff of the receiving team is trained in the correct receiving procedures, the training is done by the Pharmacist responsible for receiving.

Material handling equipment is available at receiving (i.e. Forklifts, pallet trucks), but safety equipment (loaders, protective clothing, safety shoes, hard hats, gloves, eye protection, fire extinguishers) is not always available. First-aid procedures and equipment for dealing with emergencies involving personnel at receiving is also not available. Special handling instructions are followed in respect of narcotic/psychotropic/hazardous, flammable, fragile and thermolabile products, but the activities will need to be aligned to a SOP. Drivers are not trained yet to check delivery vehicles for signs of possible external contamination

Incoming goods are checked for the correct quantity, quality, damaged containers, type, conditions and expiry dates. Delivery notes and invoices are also compared to a valid purchase orders and the receiving clerk checks the consignments against the delivery notes for the following:

- The identity of the stock
- The batch numbers of the stock
- The expiry dates of the stock
- The pack size
- The gross condition of the stock
- The quantity of the stock received
- The supplier's details
- The signature of the person who received the stock

A "discrepancy report" is unfortunately not filled in for all defective

products received, but special handling instructions are followed in respect
of narcotic, psychotropic and thermolabile products.

B. Areas with Compliance Below 50%

Compliance Area & Score	Brief description of compliance issue
Self-Inspection (0% compliance)	No written SOP or document driven system for performing regular self-inspection audits are available at CMS
	 No self-inspection questionnaire/checklist are available No results are recorded in an audit report, followed up and the corrective measures are not implemented
Contract Activities (0% compliant)	 No signed and valid service level agreements available for the following recommended outsourced activities: Pest control Collection of damaged/rejected pharmaceuticals for destruction For temperature mapping of the warehouse and fridge/cold room
Pest Control (0% compliance)	 No SOP are currently available for pest control and elimination (rodents, bats, birds, insects and termites) Pest-control agents are not used at the moment. A floor plan is not available, indicating the position of the rodent bait stations No pest control contract are in place with a register service provider
Personal Health & Hygiene (14% compliance)	 No pre-employment health checks are carried out prior and during employment at CMS on regular intervals No records are kept of all health checks of each employee Personnel at CMS is also not trained in the practices of personal hygiene The prescribed levels of personal hygiene is not always maintained by all persons who come into direct contact with the medicines in the distribution process, whether they are temporary or full-time employees or non-employees e.g. contractors or visitors Changing rooms are not available but toilets are The toilets are inside the warehouse area.
Good Housekeeping (0% compliance)	 No SOP is available for cleaning of the receiving, storage, packing and dispatch areas in the warehouse as often as needed Storage areas are not kept clean and free from accumulated waste and vermin A written sanitation program (cleaning schedule) for the warehouse is not available. Suitable equipment is also not available (i.e. brooms, mops, bins, scoops, etc.) to carry out effective cleaning
Recalls (0% compliance)	 No SOP for the recall of medicine including emergency and after hour contact persons and telephone numbers is not available No separate area for recalled goods awaiting further discussion The progress of recalls are not recorded and a final report are not issued, including reconciliation between the delivered and recovered quantities of the products

Technical Complaints	 No written SOP for handling technical complaints are available Technical complaints are not recorded, followed up and a final report is
(30% compliance)	not issued
SOPs	 A SOP does not exist for the creation and updating of SOPs
(10% compliance)	• SOPs are not uniformly structured in a format including:
	• Title
	• Date of issue
	 Policy and objective
	• Scope
	References
	 Delegation of responsibilities
	Abbreviations and definitions
	• Action
	Revision history
	Addendum
	ISO format
	SOPs are not formalized (i.e. signed, dated & initialed on each page by the
	Responsible Pharmacist and at least one of the other key personnel
	 SOPs are not structured to allow the responsible pharmacist to exercise his legal responsibilities
	SOPs are not indexed for easy retrieval
	 All superseded "Master Copies" are not archived and "Controlled Copies" are not shredded
	 All SOPs are not available at their point of use
	 SOPs are not revised at least once every 2 years
	 SOPs are not practical and suitable
	The SOPs distribution list are not appropriate
	The following minimum SOPs are also not available:
	How to create and update an SOP
	Self-inspection
	Recall / Withdrawal of medicines from the market
	Handling of technical complaints
	Rodent / Pest control
	Handling of counterfeit medicines
	Handling of goods in quarantine?
	Personal health and hygiene?
	Good housekeeping?
	Cleaning of the receiving, storage, packing and dispatch areas in the
	warehouse as often as needed
	Security of stocks on site / consignments in transit
	Training of personnel
	Cold chain maintenance
	 Distribution control of SOPs
	Stock rotation / stock control
	 Handling of scheduled medicines
	Temperature control of products

	Recording of storage conditions
	Checking validity of clients
	Planned preventative maintenance
	Counterfeit medicines
Documentation (42% compliance)	 No documents, and in particular instructions and procedures relating to any activity that could have an impact on the quality of pharmaceutical products are not available.
	 The titles, nature and purpose of each of the CMS documents are not clearly stated.
	 All CMS documents completed, approved, signed (as required) and dated by an appropriate authorized person(s) are sometimes changed without the necessary authorization
	 CMS does not establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.
	 All CMS records are not easily retrievable, and stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation
	 Documents are not reviewed regularly and kept up to date
	 CMS records relating to storage of pharmaceutical products are not kept and are also not readily available upon request in accordance with the WHO Guidelines on Good Storage Practice
	 Procedures are not in place for temperature mapping, security services to prevent theft or tampering with goods at CMS.
	 In case of temperature-sensitive pharmaceutical products, records of investigations and actions are not retained for at least one year after the expiry date of the products
Vehicles and equipment (50% compliance)	 No procedures are in place for the operation and the maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.
(ev/v companios)	 No equipment is used for monitoring conditions within the vehicles and containers.
	 CMS do not have sufficient capacity and vehicles to allow orderly storage of various categories of pharmaceutical products during transportation
Quarantined area (16% compliance)	No written SOP for the isolation and control of goods in quarantine are available
* /	A dedicated quarantine area of sufficient capacity are available
	 No adequate security measures are in place to control the movement of stock in the quarantine area
	No designated person in charge of the designated area
	No records are kept of goods in quarantine
Damaged goods	 No written procedure in place for the handling of damaged and/or
(0% compliance)	broken containers.
	 No available SOP and recording system for control of rejected goods under a quarantine system to prevent their use until a final decision is taken on their fate
Inventory Management (12%	 No effective stock control system in pace to prevent wastage through expiry, theft and fraud

compliance)	 Inventory is not rotated on a FEFO/FIFO basis No cyclical stock counts are done on a regular basis, also not according to written procedures All significant stock discrepancies are not always investigated Inventory records are not batch-specific (to enable tracing chain of supplies) Batch numbers of goods dispatched by CMS is not recorded on invoices (for traceability)
Quality Management (50% compliance)	Sections of a Quality Manual is available but the manual needs to be designed and developed
Personnel (11% compliance)	 There is no induction/orientation-training program available for new employees at CMS (personnel handbook, policy and procedure manuals) Personnel are not subjected to formal in-service quality-awareness training programs/refresher courses at planned intervals No training manuals available The training program not at least cover SOP training Legal requirements within the workplace Critical tasks Good housekeeping practices Health and hygiene Replenishment, picking, checking and packing Safety management and personal protective equipment Emergency procedures Contamination and cross-contamination Good vaccine storage and transport techniques Security No written training program including subjects to cover, frequency and assessment The training records are not filed on each employee's file CMS has a shortage of suitable trained personnel at all levels
Organization & Management (30% compliance)	 The name of the responsible pharmacist is not displayed over the main entrance The name of the pharmacist on duty is not displayed in the Depot The Site Master file is not available for the Depot An organogram is not available for CMS and also not provided at every level of the distribution chain
Transportation and products in transit (50% compliance)	 Suitable procedures (e.g. suitable coolants) are used to maintain the cold chain during the transportation process of cold chain products. The transport process for cold chain products has not been validated to confirm if the temperature of the thermolabile products are maintained at 2°C-8°C for the duration of the trip. The manufacturer does communicate all relevant conditions for storage and transportation to the entities responsible for the transportation of pharmaceutical products. (i.e. Labeling & package insert)

ANNEX 6: SCPI Training Module Objectives

Topic	Modules	SOPs covered	Objectives
SOPs	How to write and train a SOP	Applies to all SOPs	 Know what an SOP and the purpose thereof; Understand the function of SOPs; Benefits of implementation of SOPs; Understand the SOP process; SOP review and approval; Know when to renew SOPs; Create SOP checklist; Be able to structure a SOP; Be able to write a SOP; Update SOPs; Train and implement SOPs.
Operations	Process Flows	Applies to all SOPs	 How to put a flow chart together for universal understanding; The components of a flow chart; The use of flowcharts
Operations	Receiving	 Reception of stock; Control of stock in Quarantine; Control of Non-Conforming of Products; Put away of stock. 	 Comprehend what receiving stock entails; Understand documents used when receiving stock; Understand the process of receiving stock; Understand the importance of planning the receiving stock; Plan the receiving of stock; Understand special requirements for Thermo-labile, Schedule 6 and Hazardous products
Operations	Cold Chain	• Cold Chain	 What Cold Chain products are; How Cold Chain Products are transported; The Distribution Chain's role in safeguarding product quality; Storage conditions required for Cold Chain; The correct packaging, handling and timely delivery of Cold Chain products; Why proper training and awareness must be created among all role players in Cold Chain; What can be done to ensure that

Topic	Modules	SOPs covered	Objectives			
Omountions	Dialrina	B. 1. 60 1	 products are handled and transported correctly; Designated courier / freight forward partners role in Cold Chain distribution. 			
Operations	Picking, Packing and Checking	Picking of OrdersChecking and Packing of Orders	 The essential elements for picking; The picking process; Picking documentation; Packing and Checking 			
Operations	Dispatch and Distribution	 Dispatch of orders; Transportation of orders. 	 Identify the outcomes of a well-designed distribution system;; Review the distribution cycle; Discuss the elements of a distribution system and good distribution practice codes; Discuss the importance of quality assurance in distribution; Discuss planning and budgeting in distribution; Discuss the importance of data and an information system in distribution management 			
Health and Safety	Physical controls, safety and security in the warehouse Good Warehousing and Distribution Practices	 Health and Safety Inspection Sheet; Health & Safety Policy; Warehouse access & Egress Control; Daily cleaning of the Warehouse; Incident and Accident Reporting; Control of Eating, Smoking, Drinking in the warehouse; Rodent and Pest Control 	 Outline the effect of adverse (bad) storage conditions on medicines; Identify physical factors that cause damage to medicines; Discuss the physical control of factors that can cause damage to medicines; Discover a service level agreement with a service provider; Identify the role of cleaning and inspection in the warehouse; Discuss the importance of personal hygiene; Describe the rationale for safety management in the warehouse; Discuss various types of hazards found in workplaces including the warehouse; Discuss the principles of risk assessment and control; Discuss health and safety in the warehouse; Outline the composition and functions of a health and safety committee; Explain the rationale for security 			

Topic	Modules	SOPs covered	Objectives
Quality Manage- ment	Quality Management	• Recall & Withdrawal of Product's;	 considerations in a warehouse; Discuss the importance of fire precautions in a warehouse. Ensure that your facility adheres to the standards and principles of Good Warehouse Practice(GWP); Do an audit to see where the short comings are; and Suggest improvements based on audit to ensure that facility adheres to GWP Demonstrate awareness of regulatory requirements for quality control; Understand the purpose of Quality
		 Procedure for handling goods reaching expiry dates; Effective Stock Rotation; Control of counterfeit, Stolen & Damaged Product; Roles and Responsibilities: Induction Training; Storage & distribution of Products; Audits and Self Inspection; Corrective Action; Control of Documents; Control of Records; Quality management system & management reviews 	 Assurance; Understand the need for a Site Master File and a Quality Manual; How to write and train SOPs; To be able to explain quality management in a warehouse; Understand the principles of Quality Management; Management of the quality management program; How to do a quality audit; Risk management; How to put the Site Master File together as well as the need and importance of the Site Master File; Understand drug recall and destruction; How to identify counterfeits; How to conduct a recall of products.

ANNEX 7: Training Program Phase 3







SUPPLY CHAIN PERFORMANCE IMPROVEMENT (SCPI) PROGRAM TRAINING PROGRAM FOR CENTRAL MEDICAL STORE STAFF

Date /Day	Activity Description –Group 1	Activity Description –Group 2
	Week 1	
Monday, Nov 10, 2014	Group 1: CMS Managers & Supervisors Review and validation of Quality SOPs Additional modules:	Group 2 Staff doing normal duties at their place of work
	 Quality Management Program; Site Master File; SOPs – How to write and train; Warehouse Health and Safety; Risk Management. 	
Tuesday, Nov 11, 2014	Group 1 Staff doing normal duties at their place of work	Group 2: CMS Managers & Supervisors Review and validation of Quality SOPs Additional modules:
Wednesday , Nov 12, 2014	Group 1: CMS Managers & Supervisors Review and validation of Operational SOPs & Distribution staff job descriptions Introduction to Key Performance Indicators	Group 2 Staff doing normal duties at their place of work
Thursday, Nov 13, 2014	Group 1 Staff doing normal duties at their place of work	Group 2: CMS Managers & Supervisors Review and validation of Operational SOPs & Distribution staff job descriptions

	Introduction to Key Performance Indicators
Friday.	All Staff: Practical training/Work in the Warehouse
Nov 14, 2014	Warehouse rearrangement and de-junking;
	Demarcating of areas;
	Signage; and
	Cleaning.
	10h00 to 12h30: Site Visit/Tour to CIC Holdings Warehouse, Windhoek

Date /Day	Activity Description –Group 3	Activity Description –Group 4
	Week 2	
Monday,	Group 3: Theoretical Training for Supervisors	Group 4: On-the-Job Session
Nov 17,	& Workhands	Review of Key Performance
2014		Indicators
	Operational SOPs:	Review of Job Descriptions
	Receiving	
	 Put Away of Products; 	
	Picking of Orders;	
	Packing & Checking; and	
	Dispatch of Orders.	
	Additional modules:	
	Storage management and special	
	requirements;	
	Cold chain;	
	Transportation; and	
	Cycle counts & annual inventory.	
Tuesday,	Group 3: Practical training/Work in the	Group 4: Theoretical Training for
Nov 18,	Warehouse	Supervisors & Workhands
2014		Operational SOPs:
	Process flows;	Receiving;
	Planning reception of products including	Put Away of Products;
	cold chain;	Picking of Orders;
	Quality Assurance in Receiving; and	Packing & Checking; and
	Demarcation of areas.	Dispatch of Orders.
		Additional modules:
		Storage management and
		special requirements;
		Cold chain;

Date /Day	Activity Description –Group 3	Activity Description –Group 4
		Transportation; and
		Cycle counts & annual
		inventory.
Wednesday,	Group 3: Theoretical Training	Group 4: Practical training/Work
Nov 19,	Health & Safety SOPs:	in the Warehouse
2014	Health and Safety Inspection;	Process flows
	 Access and Egress control; 	Planning reception of products
	Daily cleaning;	including cold chain;
	Incident, Accident reporting;	Quality Assurance in
	Eating, Smoking and Drinking in the	Receiving; and
	Warehouse; and	Demarcation of areas.
	Pest Control.	
	Additional modules:	
	Health and Safety in the warehouse;	
	Physical controls, safety and security in	
	the warehouse.	
Thursday,	Group 3: Practical training/Work in the	Group 3: Theoretical Training
Nov 20,	Warehouse	Health & Safety SOPs:
2014		Health and Safety Inspection;
	Good warehousing and distribution	 Access and Egress control;
	practices	Daily cleaning;
	 Counting of Stock SOP; 	 Incident, Accident reporting;
	 Non-conformance SOP; 	Eating, Smoking and Drinking
	How to pack a pallet; and	in the Warehouse; and
	How to pack the truck.	Pest Control;
		Additional modules:
		Health and Safety in the
		warehouse;
		Physical controls, safety and
		security in the warehouse.
Friday,	Group 3: On-the-Job Session	Group 4: Practical training/Work
Nov 21,	Review of Key Performance Indicators	in the Warehouse
2014	Review of Job Descriptions	 Good warehousing and
		distribution practices
		 Counting of Stock SOP;
		 Non-conformance SOP;
		How to pack a pallet;
		How to pack the truck.

ANNEX 8: CMS Training Delegates Phase 3

No	Name of Incumbent	Section	Job Title	Gender	Attended >75% of training
1	Tonata Ngulu	CMS	Chief Pharmacist	Male	No
2	Girma Tadesse	CMS	IT Network Administrator	Male	Yes
3	Natasha Swartbooi	ADMINISTRATION SECTION	Administration Officer	Female	Yes
4	Felicity Tjomita	ADMINISTRATION SECTION	Administration Assistant	Female	Yes
5	Hilde Gertze	ADMINISTRATION SECTION	Senior Admin Officer	Female	Yes
6	Flavia Kistings	ADMINISTRATION SECTION	Administration Assist	Female	Yes
7	Lucia Noreses	ADMINISTRATION SECTION	Institutional Worker	Male	Yes
8	Alemnew Shibabaw	DISTRIBUTION SECTION	Pharmacist	Male	Yes
9	Ilaisa Nieto Gazquez	DISTRIBUTION SECTION	Pharmacist	Female	Yes
10	Lisbet Boffil	DISTRIBUTION SECTION	Pharmacist	Female	No
11	Yany Lopez Silva	DISTRIBUTION SECTION	Pharmacist	Female	Yes
12	Aaron Ngolonga	DISTRIBUTION SECTION	Senior Administration Officer	Male	Yes
13	Adolph Kauhonina	DISTRIBUTION SECTION	Pharmacists Assistant	Male	Yes
14	Klaus Tsei-Tseimou	DISTRIBUTION SECTION	Pharmacists Assistant	Male	No
15	Cornelius Noreseb	DISTRIBUTION SECTION	Administration Officer	Male	Yes
16	Olivia Shitumbe	DISTRIBUTION SECTION	Administration Officer	Female	Yes
17	Richard Hangara	DISTRIBUTION SECTION	Administration Officer	Male	Yes
18	Ndamonoghenda Kamati	DISTRIBUTION SECTION	Work Hand	Female	Yes
19	Terence Kanaimba	DISTRIBUTION SECTION	Work Hand	Male	Yes
20	Herman Uushona	DISTRIBUTION SECTION	Work Hand	Male	Yes
21	Philippus Antonius	DISTRIBUTION SECTION	Work Hand	Male	Yes
22	Fanuel Ambinga	DISTRIBUTION SECTION	Work Hand	Male	Yes
23	Gideon Niingo	DISTRIBUTION SECTION	Work Hand	Male	Yes
24	Gabriel Josef	DISTRIBUTION SECTION	Work Hand	Male	Yes
25	Nuuyoma Johannes	DISTRIBUTION SECTION	Work Hand	Male	Yes
26	Elistine Hangala	DISTRIBUTION SECTION	Work Hand	Female	Yes
27	Peter Uugulu	DISTRIBUTION SECTION	Work Hand	Male	Yes
28	Barnabas Kirwisa	DISTRIBUTION SECTION	Senior Pharmacist	Male	Yes
29	Odalis Gonzales Durna	DISTRIBUTION SECTION	Pharmacist	Female	Yes
30	Mirian Lopez Perez	DISTRIBUTION SECTION	Pharmacist	Female	Yes
31	Monica lilonga	DISTRIBUTION SECTION	Senior Administration Officer	Female	Yes
32	Deon Shamwanga	DISTRIBUTION SECTION	Senior Pharmacist Assistant	Male	Yes
33	Zita Ilukena	DISTRIBUTION SECTION	Pharmacist Assistant	Female	No
34	Vivoliana Kapner	DISTRIBUTION SECTION	Pharmacist Assistant	Female	No
35	Anna Shetekela	DISTRIBUTION SECTION	Administration Officer	Female	Yes
36	Alfred Lubinda	DISTRIBUTION SECTION	Administration Officer	Male	Yes
37	Alfeus Muronga	DISTRIBUTION SECTION	Work Hand	Male	Yes
38	Jonas Shikwambi	DISTRIBUTION SECTION DISTRIBUTION SECTION	Work Hand	Male Male	Yes
39 40	Levi Andreas Josef Simon	DISTRIBUTION SECTION DISTRIBUTION SECTION	Work Hand Work Hand	Male	Yes Yes
41 42	Robert Sam Tomas Nghindibwasha	DISTRIBUTION SECTION DISTRIBUTION SECTION	Work Hand Work Hand	Male Male	Yes Yes
43	Stella Uiras	DISTRIBUTION SECTION DISTRIBUTION SECTION	Work Hand	Female	Yes
44	Washe Ferdinant	DISTRIBUTION SECTION	Work Hand	Male	Yes
45	Seija Nakamhela	PROCUREMENT & TENDERS	Senior Pharmacist	Female	No
46	Eddyson Kaujama	PROCUREMENT & TENDERS	Senior Administration Officer	Male	No
47	Harriet Lema	PROCUREMENT & TENDERS	Pharmacist	Female	No
48	Bizuayehu A Lemesa	PROCUREMENT & TENDERS	Pharmacist	Male	No
49	Leontine Shikukutu	PROCUREMENT & TENDERS	Senior Pharmacist Assistant	Female	No
50	Saima Shikongo-Johannes	DISTRIBUTION SECTION	Administration Officer	Female	Yes
30	Janua Jinkongo-Jonannes	DISTRIBUTION SECTION	Administration Officer	Terriale	163

ANNEX 9: Sample SOP Implementation Checklist

This document contains highly confidential information; therefore it should not be disclosed to anyone except the Assessor, Trainee, and Management



SOP-CENTRAL MEDICAL STORES NAMIBIA-0001-RECEIVING OF STOCK

Work Instruction: SOP-CENTRAL MEDICAL STORES NAMIBIA-0001-RECEIVING OF STOCK

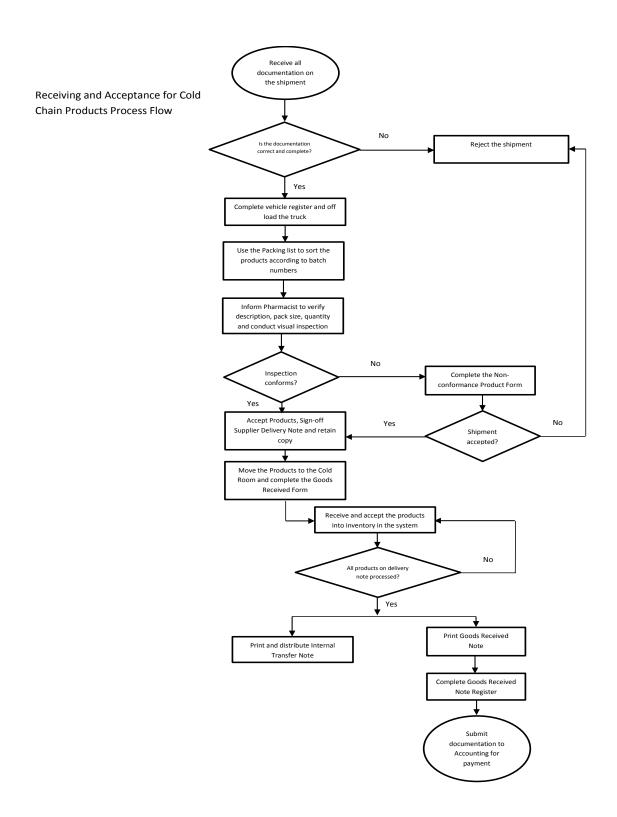
Expected Learning Outcome Statement:

No.	Step	Implementation Comment		Comment
		Yes	No	
1	Maintain security by ensuring that the Receiving bay doors remained closed at all times except during receiving and transfer of products to the warehouse. If the main receiving door is open the internal receiving door should be closed, and if the main receiving door is closed the internal receiving door should be open.	X		
2	All goods received, shall be processed in Syspro within 48 hours of receipt.	X		
3	A list of products which require special storage or handling instructions (Thermolabile / narcotic/ psychotropic medicines) shall be available and consulted on receipt of stock.	X		
5	The site security shall hand over the documentation to the Pharmacist Assistant and/or Clerk at the CMS Receiving Bay who will confirm that the consignment is for CMS, and assemble all relevant documents from the supplier, which are required for receiving a new consignment. Documents required are: Delivery note; Purchase Order; Packing list (only for ARV's, TB and Vaccines); Certificate(s) off analysis; Verify the description, pack size, quantity indicated on the delivery note against the purchase order in the system. Make sure the generic name of the medicine or description of the clinical supply delivered is the same as that mentioned on the Purchase Order.	X		

	If all conditions are met, follow the next step, otherwise inform the Procurement Section and act accordingly. NB: No goods should be accepted until all the documentation agrees			
6	If all the documentation is not received or does not agree or is not completed the Pharmacist assistant should consult with the Distribution Pharmacist if shipment should be rejected.	X		
7	If all the documentation is in order, and agree the shipments should be accepted.	X		
8	Security shall complete the vehicle register every time stock gets delivered before offloading the truck.		X	Was implemented before the end of the week
9	Security shall then arrange the opening of the Receiving doors in conjunction with the Pharmacist Assistant and or Clerk at the CMS Receiving Bay.	X		
10	Security together with the Pharmacist Assistant and/or Clerk shall check the inside of the truck for any obvious contaminants and de-dust the box (es) or pallet(s) using a damp cloth before offloading.	X		
11	Offload the truck.	X		
12	If more than one truck is to be offloaded, determine the unloading priority as follows: High Priority: • Products currently in short supply or out of stock;			
	 Heat sensitive products such as vaccines; Controlled items; 	X		
	Low Priority: First come first served basis for all other products.			
13	Verify the description, pack size, quantity.	X		
14	Conduct visual inspection of the consignment received Job aid No. A-6 "Conduct Visual Inspection sheet" attached.		x	Visual inspection sheet was implemented before the end of the week
15	Invite the Distribution Pharmacist or any designated Pharmacist, if Schedule 4 items or ARV's are to be inspected.	X		
16	If a discrepancy is noted, fill in a "Non-Conformance Product form".	X		
17	Have the driver co-sign the "Non-Conformance Product form" and give a copy to the driver before departure for submission to the supplier/shipper.	X		
18	If the consignment or part thereof is rejected, hand the shipment back to the driver for return to the supplier.	X		
19	If everything is in order with the shipment, sign off the Delivery Note, give a copy to the driver of the vehicle and retain a copy.	X		
20	Sort products according to different batches and expiry dates and place the products on pallets. Ensure that the stacking of the pallets does not exceed 1.3 meter high.	X		
21	Receive goods into Inspection in Syspro Accept the goods into inventory in Syspro, refer to Job Aid No. A – 8 + A -5.	X		
22	Determine if the incoming goods should be subjected to post purchasing testing, according to directives provided by the Procurement Unit and/or QSL (Quality Surveillance Laboratory), and sample appropriately.	X		
23	If sampling is needed follow SOP – follow 9 below.	X		
24	Generate a Goods Received Note (GRN) Report for the supplies received and accepted.	X		

25	Generate an Internal Transfer Note (ITN – 1) Job Aid No. A – 10 attached, in duplicate to transfer the supplies	X	
	to the appropriate warehouse.		
26	Distribute the ITN to the appropriate Warehouse.	X	
27	Ensure that the ITN – 1 is signed by the appropriate Warehouse Pharmacist Assistant or Clerk upon transfer of	X	
	the goods to the appropriate warehouse.		
28	One signed copy of the ITN-1 is released to the appropriate warehouse and the original is archived without delay.	X	
29	Complete the GRN to Accounts Register, and forward all the relevant documents		
29	Covering the, GRN Report, Packing List and Delivery Note to Accounts Section to initiate supplier payments	X	
30	All pre acceptance procedures for goods receiving shall also apply for cold chain goods.	X	
31	All Cold Chain products should take preference.	X	+
31		A	
32	The Materials Handling Clerk-Receiving shall be responsible for transferring all Cold Chain items to the	X	
	refrigerator within 15 minutes of Receipt (defined as goods being offloaded from the truck).		
33	The Receiving Pharmacist or designate shall complete all the applicable fields in the Cold Chain Product Register.	X	
34	The Cold Chain Product Register shall be signed and checked by the Receiving Pharmacist.	X	
	Upon receipt into the fridge, the box (es) containing fridge items shall be opened up and removed from the		
35	insulating container(s) ensuring all contents are exposed to the Cold Chain conditions and thereafter placed in	X	
	appropriate locations within the fridge.		
	The Receiving Pharmacist or designate shall check the temperature monitoring devices (for those products that		
36	have these included in a shipment); verify that temperatures were maintained between 2-8 degrees Celsius	X	
	and/or that the delivery was received within the prescribed requirements for the product.		
37	If a break in the Cold Chain is confirmed or suspected, the Receiving Pharmacist/Designate shall not receive the	X	
37	product, but send it back.		
38	All pre acceptance procedures for goods receiving shall also apply for Schedule 4 and Security items.	X	
39	Use the packing list to sort the products according to batch numbers.	X	
40	Fill in a GRF. Refer to job aid A-4 Goods Received Form.	X	
41	Invite the Distribution Pharmacist or any designated Pharmacist to inspect the Schedule 4 and Security	X	
41	Products.	A	
42	If any item fails visual inspection, place consignment under quarantine, and await further instruction of the	X	
42	Distribution Pharmacist.	Λ	
43	Have the driver co-sign the "Non-Conformance Product form" and give a copy to the driver before departure	X	
43	for submission to the supplier/shipper.	Λ	
44	If the consignment or part thereof is rejected, hand the shipment back to the driver for return to the supplier.	X	
45	Accept goods into inventory in Syspro.	X	
46	Determine if the goods should be subjected to sampling, follow the procedures Sampling of stock, if not print	X	
40	and distribute the Internal Transfer Note.	Λ	
	Result	95%	

ANNEX 10: Sample CMS Updated Process Flow



ANNEX 11: Sample SOP

	STANDARD OPERATING PROCEDURES	DEPT: QUALITY ASSURANCE SOP NO: SOP-CENTRAL MEDICAL STORES NAMIBIA- SOP 0003 - CONTROL OF NON-CONFORMING PRODUCT
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TITLE	SOP-CENTRAL MEDICAL STORES NAMIBIA – SOP 0003 - CONTROL OF NON- CONFORMING PRODUCT							
APPROVED BY:	DATE:							
APPROVED BY:				DATE:				
APPROVED BY CONTROL:			DATE:					
EFFECTIVE DATE:		REVIEW DATE:		SUPERSEDES:	SOP-CENTRAL MEDICAL STORES NAMIBIA -0004- PUT - AWAY PRODUCT			

1. Purpose:

To provide guidelines on identifying and eliminating the cause of potential non-conformities or other undesirable situation.

Scope:

All potential non-conformances identified at CMS are to be documented and controlled so that continual improvement is enforced.

3. Responsibilities:

Title	Responsibility
Section Heads	Shall ensure that Preventative Actions are investigated and implemented, and their effectiveness assessed and documented.
Quality Assurance Pharmacist	Are responsible to ensure that Preventative Action Records are maintained, retained and forwarded to the Management Representative.

4. Definitions:

Term	Definition
Preventative Action	Action required to eliminate the cause of potential non-conformity or other undesirable situation, and to prevent occurrence.
Management Representative	A person appointed and given authority by top management to manage, monitor, evaluate and coordinate the quality management system.

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ANNEX 12: Sample Job Description

MINISTRY OF HEALTH AND SOCIAL SERVICES

JOB DESCRIPTION

SECTION 1: JOB IDENTIFICATION						
Job category:	Warehousing					
Job title:	Administrative Officer					
Directorate:	Tertiary Health Care & Clinical Support Services					
Division:	Pharmaceutical Services					
Subdivision:	Central Medical Stores					
Work Location:	Warehouse					
Name of job holder:						
Direct supervisor:						
No. of subordinate(s):	Directly: Indirectly:					
Date of appointment in the post:						
Date of appointment in the Public						
Service:						

SECTION 2: PRIMARY PURPOSE OF THIS POSITION

To ensure that the day to day tasks and activities related to customer order processing and warehouse management are running smoothly, efficiently and effectively in accordance with the current SOPs, policies and guidelines in force. This will enable the achievement of operational goals and objectives.

SECTION 3: KEY RESULT AREAS/KEY PERFORMANCE AREAS

- 1. Adhere to CMS policies and procedures
- 2. Self-inspection / Audits
- 3. Stock management and inventory control
- 4. Order processing
- **5.** Housekeeping
- **6.** Supervisory tasks and activities
- 7. General
- 8. Handling of documentation
- **9.** Adhere to all SOPs
- 10. Adhere to all health and safety rules
- 11. Immediately report health and safety offences and shortcomings to the supervisor and health and safety representative

SECTION 4: DUTIES AND RESPONSIBILITIES ON THE KEY PERFORMANCE AREAS							
Performance areas	Duties						
SOPs and Process Flows	Adhere to CMS policies and procedures.Complete training and re-training on SOPs as required.						
Self-inspection / Audits	 Prepare for Audits. Write and submit corrective actions with time lines. Implement corrective actions as required. 						
Stock management and inventory control	 Ensure that the products transferred from the receiving bay into the warehouse under control meets the set specifications, in all aspects, and conforms to the accompanying transfer documents, in terms of description, pack size, quantity, quality and standard. Arrange stock in a logical sequence in the warehouse in pre-allocated and labelled spaces (bins), on an on-going and a continuous basis. Ensuring that all shelf labels reflect current products and issue units. Ensure that the FEFO principle is followed. Monitor stock expiry dates and remove expired 						
	 products every month end and complete the necessary product disposal form for the approval of your supervisor. Monitor stock movement and complete weekly and monthly reports regarding the stock movement trends. The report should include min/max report, stock out, low stock and overstock. 						
	Manage products in quarantine, ensuring that the products are not picked until cleared.						
Order processing	 Promptly and accurately process main, emergency and interim orders according to the picking slips. Ensure that goods issued out reflect the original customer order in terms of item description and quantities ordered. With the Pharmacists approval issue alternative/substitute products in case of no stock available of original ordered product. Label boxes with the customer's name to allow easy checking. 						
	 Amend the final picking slip that is forwarded to Dispatch, to reflect stock physically picked. Investigate and prepare responses to customer queries and complaints made against items, which were issued from the warehouse. 						

Performance areas	Duties							
Housekeeping	 Prepare and implement a roster for the cleaning of the floor and shelves in the warehouse. Arrange the stock in a logical sequence on the shelves and on the pallets on an ongoing basis in order to maintain an orderly stock arrangement at all times. Ensure that your warehouse is locked at all times if no picking is taking place. Monitor and maintain an accurate log of room temperature in the designated warehouse and alert the Head of Distribution of any deviations from set standards. 							
Supervisory tasks and activities	 Prepare a daily schedule of tasks and activities and allocate the same to the subordinate staff working under you. Supervise, monitor and control the subordinate staff working under you. Perform the Senior Administrative Officer's supervisory responsibilities in his/her absence, whenever requested by the head of section. To attend to personnel matters for the subordinate staff, including initiation of disciplinary action in cases of misconduct and breach of public service staff rules 							
General	 Perform any other tasks, duties and responsibilities as may be assigned by the head of section from time to time. Safeguard the safety, security and integrity of public property in the section, including products, buildings, office furniture, machines, equipment and tools. 							
Handling of documentation.	File all documentation needed for any official records.							
Shared Competencies.	Good communication with colleague's and clients.							
Degree of supervision received:	Significant							
Degree of planning necessary:	Significant							
Adverse working conditions:								

SECTION 5: COMMUNICATION RELATIONSHIP					
5.1 Internal Staff members in CMS					
5.2 External	None				

SECTION 6: PERSON SPECIFICA	TION
5.1 Education/Professional	
qualification required for the position	
5.2 Specific work experience	Basic supervisory skills
prescribed	1
5.3 Skills and Competencies	Knowledge of Good Warehousing and Distribution
	Practices
	Basic numeracy and literacy
	Communication skills
	Ability to work in a group/team
	Basic computer skills

SECTION 7: ACKNOWLEDGEMENT I the undersigned employee states that the above job description was read and understood and where necessary effectively explained to me. I hereby accept the above as my duties. I accept further any reasonable instruction from my superiors in the interest of my employer and the fact that the above Job Description may be reviewed and amended at any time in the interest of my employer.

ANNEX 13: Self- Assessment Checklist Results after Phase 4

No	Organization and management	Yes	No	Not Sure	Problem	Audit 1	After Training – Audit 2
1	Is the Depot appropriately licensed with the regulatory authority to perform the intend functions in terms of the applicable legislation?					The Pharmacy Act just talks about a Pharmacy Establishment but is not clear about being appropriately licensed. At this stage Public Health Facilities are automatically licensed to keep medicines.	
2	Is the name of the responsible pharmacist displayed at the main entrance?					Awaits the final appointment of the Responsible Pharmacist.	
3	Is the name of the pharmacist on duty displayed in the Depot?					Recommended	
4	Are distributor operations conducted under the constant personal supervision of a pharmacist?						
5	Is a Site Master file available for the Depot?					A Site Master File (SMF) is recommended to demonstrate that the site is ready for any inspection, and that a basic quality system is in place. It is useful in identifying any gaps in the quality system.	The Site Master will be implemented once accepted and signed.
6	Is an appropriate organogram provided at every level of the distribution chain?					Recommended	
7	Are letters of appointment available for key supervisory personnel?					Not confirmed that everyone has appointment letters. Need to check the employment file.	
	Personnel						
8	Is there an induction/orientation-training program available for new employees? (personnel handbook, policy and procedure manuals)					Induction/orientation- training program needs to be developed and introduced to new staff.	
9	Are personnel subjected to formal in-service quality-awareness training programs/refresher courses at planned intervals? – Are training manuals available?					A quality awareness program and Training manuals need to be developed and introduced.	Training manuals were delivered to CMS after the training.
10 11 12 13 14 15 16 17 18 19 20	Does the training program cover (at a minimum): SOP training Legal requirements within the workplace? Critical tasks? Good housekeeping practices? Health and hygiene? Replenishment, picking, checking and packing? Safety management and personal protective equipment? Emergency procedures? Contamination and cross-contamination? Good vaccine storage and transport techniques? Security?					A training program/manual needs to be developed and introduced.	The training manuals and program covers everything.
21	Is there a written training program including subjects to					Needs to be developed.	Developed and delivered.

	cover, frequency and assessment?			
22	Are training records filed on each employee's file?		Needs to be developed.	
23	Are current and authorized job descriptions available for key personnel?		This needs to be checked to see if every employee has a job description and if the workers understand what is expected of them.	Developed and delivered.
24	Are there sufficient suitable qualified and trained personnel at all levels?		Recommended – Inventory controller as well as HR at CMS.	
25	Are personnel issued with Personal Protective Equipment (e.g. protective clothing, hand gloves, respiratory masks, eye goggles or hard hats) for the safe handling of pharmaceutical goods where applicable? Procurement of medicines		Some items are missing.	
26	Are goods purchased only from legitimate manufacturers or other authorized sources to ensure traceability and confidence in the quality of pharmaceutical products?		N/A	
	Quality Management			
27	Is a Quality Manual available?		Managing quality services and products a Quality Manual needs to be designed, covering key activities carried out in the business, ensuring that all processes deliver quality products / services up to final delivery.	Designed and delivered.
28	Does the organogram include key supervisory/control personnel? Are the responsibility, authority and interrelationships of all personnel clearly defined?		Needs to be developed and displayed against the entrance wall of CMS – Awaits appointment of some personnel.	CMS are in the process of re defining its organogram as approved by the PS
	Premises, warehousing and storage			
29	Is access to the Receiving Department secure and restricted to authorized persons only?		Receiving needs to be reorganized. Security training is needed.	SOP implemented
30	Does receiving bays protect deliveries from bad weather during unloading?		There is no protection for deliveries from bad weather conditions.	
31	Are these areas effectively separated and clearly defined?		Floor plan needs to be re- designed for better workflow and optimal use of space.	SOP implemented
32	Is the receiving area designed and equipped to allow the cleaning of containers of incoming goods, if necessary, before storage?		There is a need of clearly demarcated areas. Current markings are inadequate.	Clearly demarcated areas.
33	Is there a receiving team available during receiving? (Supervisor/pharmacist, receiving clerks, of loaders/loaders, forklift operators, cleaners, security)?			Receiving Pharmacist Assistant with work hands and
				Pharmacist as required
34	Is all staff of the receiving team trained in the correct receiving procedures?		Reception of products is not planned and scheduled in advance – products are received whenever they arrive.	Pharmacist as
34			planned and scheduled in advance – products are received whenever they	Pharmacist as required Training was

	protective clothing, safety shoes, hard hats, gloves, eye protection, fire extinguishers)		safety representatives develop a health and s file.	safety	representative s established, equipment will be procured as soon as budget is available
37	Is first-aid procedures and equipment for dealing with emergencies involving personnel at receiving available?		No first-aid training is need to appoint Firs representatives and de SOPs.	st-aid	SOP was developed but not implemented 100%
38	Are special handling instructions followed in respect of narcotic/psychotropic/hazardous, flammable, fragile and thermolabile products?		Needs to be checked according to SOP.		
39	Are goods and delivery vehicles examined for signs of possible external contamination?		Drivers are not trained perform activity.	d to	SOP implemented
40	Are incoming goods checked for quantity, quality, damaged containers, type, conditions and expiry dates?		Need to update curren receiving SOP and ob		
41	Are delivery notes and invoices compared to a valid purchase orders?		Described Control		
42 43 44 45 46 47 48 49	Do receiving clerks check consignments against delivery notes for the following: • Identity of stock? • Batch numbers of stock? • Expiry dates of stock? • Pack sizes? • Gross condition of stock? • Quantity of stock received? • Supplier's details? • Signature of person(s) receiving stock?		Receiving - Goods are properly labelled. NB - Sometimes deci are overruled by Distr Pharmacist.	isions	
50	Are "discrepancy reports" completed for all defective products received? (integrity, short-dated, expired, broken, leaking, damaged, short/over supply)		Stock is sent back wit discrepancy reports.	Stock is sent back without discrepancy reports.	
51	Are special handling instructions followed in respect of narcotic, psychotropic and thermolabile products?		There is no cold chair available.	n SOP	·
	General storage area				
52	Are the storage areas of sufficient capacity to allow orderly storage of various categories of products namely products in quarantine, released, rejected, returned or recalled products?		Currently stock is stored all over. Housekeeping is non-existent. With better planning space for quarantine, rejected and returned products will become available.		
53	Are there any open drain channels in the floor?				
54	Are the premises clean and floors durable and easy to clean?		is poor and training is needed.	raining wa ousekeep	as done on ing
55	Are walls solid and sealed?		Walls are in need of paint.		

56	Is the premises constructed in such a way to prevent infestation by vermin and pests?		Problem area.	
57	Is waste material collected in suitable containers (with closable lids) for removal to dedicated collection points at regular intervals?		There are no waste containers within the warehouse.	Waste material are collected in a designated area outside of CMS
58	Are goods adequately protected from light, heat and humidity?			
59	Are the floor areas sufficient and organized to facilitate adequate security, efficient flow of work and people, effective communication/supervision and optimum service delivery to clients?		It is needed to reorganize the floor plan.	Floor space are utilized more effectively
60	Is there a Fire Safety Procedure available?		Inadequate – no fire safety floor plan available.	SOPs developed
61	Is there sufficient fire-fighting equipment available, both inside and outside the building?		Currently stock is placed in front of some fire-fighting equipment.	Equipment are available and was recently serviced
62	Are emergency exits clearly marked?		Strongly advised.	SOP developed but not 100%implemented
63	Are emergency exits regularly checked to ensure that they are not blocked or inaccessible?		The emergency door is locked, and products are stacked against the door on the outside.	SOP developed but not 100%implemented
64	Are sufficient smoke detectors available?	П		
65	Are the fire extinguishers serviced every 12 months?			
66	Are fire drills executed at least once per month?			Health and Safety rep was appointed and he and his committee will see to it that it is done.
67	Is the fire alarm linked to the local fire brigade?	П		
68	Do the premises have a First Aid Box complying with the specifications?		Available but not replenished – currently no training for first aid and no First aid representatives.	
69	Are storage areas provided with adequate lighting to enable all operations to be carried out accurately and safely?		More lights recommended.	Damaged lights was repaired
70	Are Material Safety Data Sheets (MSDS) available for each type of product stored in the warehouse?		To be designed.	
71	Is a Chemical Spillage Kit available? (Is an SOP available on the cleanup of any spillage to ensure complete removal of any risk of contamination?)		No SOP for Chemical Spillage Cleanup.	SOP designed but not 100% implemented
72	Are all pharmaceutical products handled and stored in such a manner to prevent contamination, mix-ups and cross-contamination?		Need to reorganize the layout of the warehouses.	Space is utilized better
73	Are forklifts, hand trucks, cranes, hoists only operated by trained operators?		NB — Operators have never been trained.	Forklift drivers was trained recently

74 75 76 77 78 79 80 81 82	Are the storage areas of sufficient capacity to allow orderly storage of the various categories of products, namely products in dedicated, demarcated areas:			The layout needs to be reorganized to make space available.	Space is utilized better, still not enough space in the facility
83	Are storage conditions for pharmaceuticals in compliance with the labeling/package insert, which is based on the results of stability testing?				
84	Are medicines stored according to a system (e.g. computerized or bin card system)? Also in various stores or sections.				
85	Are all goods stored off the floor, on pallets, shelves in cupboards or pick flow racks, suitably spaced to permit cleaning and inspection?			Some products are stored directly on the floor without pallets.	Good improvement at CMS
86	Are pallets kept in a good state of cleanliness and repair?			Pallets are stored in the yard in the sun and weather. The pallets need to be stored properly.	
87	Is enough space provided between storage and outside walls to allow access for rodent/insect control, cleaning and firefighting equipment and materials?			Products stored directly against outside walls	Space constraints won't allow
88	Is the warehouse dedicated to "approve" saleable stock only? Is physical or other validated segregation (e.g. electronic) provided for the storage of rejected, expired, recalled or returned products?			Clearly demarcated areas are needed.	Demarcated areas were available and used in the receiving area. Cages are used at dispatch
89	Is broken or damaged items withdrawn form usable stock and separated?			Not at all times.	
90	Is the temperature in the warehouse according to specifications?			Need to check records?	
91	Are calibrated temperature recorders/maximum-minimum thermometers used to record the temperature?				Temperature recorders (thermometers) are available in all the warehouses.
92	Are the temperatures of the warehouse monitored with calibrated temperature monitors and recorded twice a day?				Temperature records are available but not completed regularly by all the warehouses.
93	Are flammable substances (e.g. Ether) stored in separate outdoor flammable store located away from the main building and pathways?				
94	Are any expired/short dated (3 months) medicines on the shelves?				
	Termolabile store				
95	Are thermolabile medicines stored in a fridge/cold room?				

96	Only medicines are stored in the fridge/cold room?							
97	Are thermolabile medicines stored according to a document driven system and SOP?			SO	P - n	chain eeds to loped.	SOF	P developed
98	Is the consignment of vaccines checked on receipt and transferred to the fridge/cold room immediately?							
99	Does the Warehouse Designate check the temperature monitor indicator within the cooler box to ascertain whether the delivery was maintained and received within the prescribed requirements of 2°C - 8°C?							
100	Does the Warehouse Designate record all these details on the Cold Chain Maintenance log?				inten	Chain ance	?	
101	Is the fridge/cold room in working order and maintained regularly as per contract? Is maintenance recorded?			No reco		ntenance		
102	Are vaccines stored in the middle shelves of the fridge? (avoid placing stock on door, top and bottom shelves)		I	N/A				
103	Are temperatures monitored in the fridge/cold room with calibrated temperature recorders/maximum-minimum thermometers and recorded twice daily? Temperature logs?			Need to make sure the fridge, recorders, min. and maximum thermometers are calibrated – need to see the measures they use for calibration.				
104	Is an adequate warning system in place to indicate power, fridge or cold room failure?					SMS's.		
105	Is a back-up generator in place for the fridge/cold room?							
106	Is the back-up generator tested at least once per week?			Q	uarte	erly		
107	Are procedures in place for maintaining the cold chain in the event of fridge failure?			tra	ainin	_	SOI dor	P available. Training ne.
108	Are vaccines quarantined after a "cold chain failure" and is the "cold chain variance form" completed?			tra	ainin	_	SOI dor	P available. Training ne.
109	Are the temperature recorders/ maximum-minimum thermometers in the fridges/cold room and cool boxes calibrated at defined intervals?				old c onite			
	Inventory management							
110	Is there an effective stock control system in pace to prevent wastage through expiry, theft and fraud?					Need to g through the system to ensure whis needed, and how t put a control system in place.	ne nat ,	MSH is busy working on a eLMIS system
111	Is inventory rotated on a FEFO/FIFO basis?			Need to reorganizz stock and clearly mark box with the expiry da			es	Not enforced at all the warehouses, was emphasized
112	Are cyclical stock counts done on a regular basis, according written procedures? Are the actual and recorded stocks compared?	to	Stock taking system			taking	oe e	Cycle counts are not done, waiting for authorization to pay overtime on a Saturday

					developed and put in place for regular stock take, as well as feedback records.	for cycle counts
113	Are all significant stock discrepancies investigated as a check against inadvertent mix-ups and or incorrect issue?				SOP to be developed and put in place.	SOP available. Training done. Implementation needed
114	Are all real-time computerized inventory records kept?					
115	Are inventory records batch-specific (to enable tracing chain of supplies)?				Only for specific items.	
116	Are the batch numbers of goods dispatched by the company recorded on invoices (for traceability)?					Done for ARV's
117	Are medicines supplied into the retail sector to authorized clients?					
118	Are there up-to-date lists of registered Hospitals, pharmacies, veterinarians and licensed dispensing practitioners (client validity)?	fo		- ne pr	eed oject	
	Returned goods					
119	Is there a written SOP or document-driven system for the handling of returned goods?				Have to be updated, formatted and signed off.	
120	Are all the examination, assessment and decisions regarding the integrity of the returned goods channeled through a pharmacist?					
121	Are returned goods separated from saleable/useable stock until their final disposal?					
122	Are batch-specific records kept on all goods returned?				Only for some items	
123	Does a designated pharmacist formally release goods for return to stock?					
	Damaged or rejected goods				N 1 1	600 11.11
124	Is there a written procedure in place for the handling of damaged and/or broken containers? Is particular attention paid to potentially toxic and hazardous products?				Need to be designed.	SOP available and implemented. Training done.
125	Is there an SOP and recording system for control or rejected goods under a quarantine system to prevent their use until a final decision is taken on their fate?				Need to be designed.	SOP available and implemented Training done.
	Quarantine area					
126	Is there a written SOP for the isolation and control of goods in quarantine?				To be developed.	implemented. Training done.
127	Is a dedicated quarantine area of sufficient capacity available?				To be organized in receiving area.	Available, space remains a challenge
128	Are quarantined goods clearly identified as such?					
129	Are adequate security measures in place to control the movement of stock in the quarantine area?				Needs to be developed and put in place –	SOP available and implemented. Training done.

				training is	
	T 1 ' (1 ' 1 C(1')			needed. Needs to be	Description
130	Is a designated person in charge of this area?			appointed.	Receiving Pharmacist
-	Are records kept of goods in quarantine?		-	Needs to be	Assistant SOP available
	Are records kept of goods in quarantine?			developed.	and
131					implemented.
					Training done.
	Vehicles and equipment				
	Are the vehicles that are used for the delivery of				
	pharmaceutical products dedicated and appropriately				
132	protective of the products to prevent exposure to conditions				
	that could affect their stability and packaging integrity, and				
	prevent contamination of any kind?				
	Does the design and use of the vehicles and equipment aim to				
	minimize the risk of errors and permit effective cleaning in				
133	order to avoid contamination, build-up of dust or dirt and/or				
100	any adverse effect on the quality of pharmaceutical products				
	being distributed?				
	Are there procedures in place for the operation and the			To be	SOP available.
124	maintenance of all vehicles and equipment involved in the			developed,	Checklists
134	distribution process, including cleaning and safety			implemente d and	developed and
	precautions?			trained.	training done.
	Where special storage conditions (e.g. temperature and/or			Not	
105	relative humidity) are required during the transit of medicines			monitored.	
135	are these storage conditions provided, checked, monitored and				
	recorded?				
	Are equipment used for monitoring conditions within vehicles				Checklists
136	and containers e.g. temperature and humidity, calibrated?				developed and
					training done.
	Are vehicles and containers of sufficient capacity to allow			Cold chain vehicles	
137	orderly storage of various categories of pharmaceutical			needed.	
	products during transportation?			necaca.	
	Shipment containers				
138	Are thermolabile products dispatched in cold chain containers?				Training done
	Is special care taken when using freezer packs to ensure that			Need	
139	pharmaceutical products do not come into contact with freezer			training.	
	packs, as it may have an adverse effect on the quality of				
	products?				
	Are all pharmaceutical products stored and distributed in				
140	containers which do not have an adverse effect on the quality				
140	of the products, and which offer adequate protection from				
	external influences, including microbial contamination?				
	Are labels applied to the container clear, permanently fixed to			-	
141	the container and indelible? Does the information on the label				
141	comply with applicable national legislation with regard to the				
	labeling of containers?				
142	Are special transport and/or storage conditions stated on the				
142	label?				
	Dispatch control				
143	Is there a written SOP relating to the control of goods				
1 73	dispatched to the clients?				
144	Does the SOP require that client validity/authority to acquire				
144	such products be verified?		N	A	
		1			1

145	Do dispatch bays protect deliveries from bad weather during loading?			
146	Is there a current list of approved, valid customers?		Not updated.	
147	Are records for the dispatch prepared and does it include the following information: Date of dispatch? Name and address of supplier? Name and address of addressee? A description of the products? Assigned batch number and expiry date? Applicable transport and storage conditions? Unique number to allow identification of the delivery order?		Need training.	SOP developed and implemented.
148	Are the vehicles and containers loaded carefully and systematically on a first out/last-in basis in order to save time when unloading and to prevent physical damage?			SOP available and implemented. Shortage of workhands
149	Does the packaging material used adequately protect goods whilst in transit?			Products are packed in boxes and identified on the outside
150	Are suitable procedures in place to clean up spillages in transport vehicle as soon as possible to prevent possible contamination and cross contamination?		SOP and training is needed.	SOP available. Training done.
151	Have the designated personnel of the Depot courier service been trained in "cold chain management" of the transport of thermolabile products?		Drivers are not trained.	Drivers that were available were trained
152	Are suitable procedures used to maintain the cold chain? (suitable coolants, insulation material)			
153	Are thermolabile products adequately protected from being compromised? (products/temperature probes are wrapped in bubble packs and isolated from freezer blocks)			
154	Are written procedures in place to investigate and deal with any "cold chain failure" and is a "cold chain variance form" completed?		SOP and training is needed.	SOP available. Training done.
	Transportation and products in transit			
155	Are suitable procedures (e.g. suitable coolants) used to maintain the cold chain during the transportation process of cold chain products?			
156	Has the transport process for cold chain products been validated to maintain the thermolabile products at 2°C -8°C for the duration of the trip?		Cold chain truck might be a good idea.	
157	Does the manufacturer communicate all relevant conditions for storage and transportation to the entities responsible for the transportation of pharmaceutical products? (Labeling & package insert)?			
158	Are cold chain products being preserved while in transport? The storage conditions of the products are not grossly exceeded for an unacceptable length of time?		Validation is a problem	
159 160	 Are products transported in such a way that: The identification of the product is not lost? The product does not contaminate, and is not contaminated 			

	by, other products or materials?			
161	Adequate precautions are taken against spillage or breakage?			
162	• The specific storage conditions of the product are not interfered with?			
	Documentation:			
163	Are documents, and in particular procedures relating to any activity that could have an impact on the quality of pharmaceutical products, designed, completed, reviewed and distributed with care?		Needs to be designed and trained.	SOPs available. Training done. Not all documents that was designed is implemented
164	Are the title, nature and purpose of each document clearly stated? Are the contents of the documents clear and unambiguous? Are documents laid out in an orderly way and easy to check?		Need to confirm.	All official books are clearly marked on the out side
165	Are all documents completed, approved, signed (as required) and dated by an appropriate authorized person(s) and should not be changed without the necessary authorization?			Documents that requires authorization is authorized by the Distribution Pharmacist
166	Do the nature, content and retention of documentation relating to the distribution of pharmaceutical products comply with national legislative requirements? Where such requirements are not in place, are these documents retained for a period equal to the shelf-life of the products where applicable, plus one year?		Minimum of 5 years.	
167	Does the distributor establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation?		Some of the documents are archived and cannot be retrieved easily.	
168	Are all records easily retrievable, and stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation?		Some of the documents are archived and cannot easily be retrieved.	
169	Are documents reviewed regularly and kept up to date?		Training needed.	Training was done and all documents were reviewed. This needs to be done bi-annually.
170	Are records relating to storage of pharmaceutical products kept and readily available upon request in accordance with the WHO Guidelines on Good Storage Practice?		Training needed.	QMS are available but not implemented 100%
171	Are procedures in place for temperature mapping, security services to prevent theft or tampering with goods at the storage facilities, destruction?		Training needed.	SOP available but not yet 100% implemented. Staff Trained
172	In case of temperature-sensitive pharmaceutical products, are records of investigations and actions retained for at least one year after the expiry date of the product?		Training needed	
173	Where the records are generated and kept in an electronic format, are backups maintained to prevent any accidental loss of data?			

		_	 		
174	Does the holder of a distribution license keep records for any transaction in medical products received or dispatched containing at least the following information: Date? Name of the medical product? Batch number and expiry date? Copies of order forms, delivery notes, stores receipt and issue vouchers? Quantity received? Quantity supplied? Name and address of the approved supplier or consignee?				
	Standard Operating Procedures				
175	Does a SOP exist for the creation and updating of SOPs			Needs to be developed.	SOP available. Training done.
176	Are all SOPs uniformly structured in a format including the: Title? Date of issue? Policy and objective? Scope? References? Delegation of responsibilities? Abbreviations and definitions? Action? Revision history? Addendum? ISO format?			Not in the correct format. SOPs needs to be reviewed, formatted and signed off.	SOPs available. Reviewed, written in the correct format and training done.
177	Are all SOPs formalized? (signed, dated & initialed on each page by the Responsible Pharmacist and at least one of the other key personnel)			Await the appointment of the Responsible Pharmacist.	Acting Chief Pharmacist will sign the documents
178	Are the SOPs structured to allow the responsible pharmacist to exercise his legal responsibilities?				Yes
179	Are the SOPs indexed for easy retrieval?			All SOPs are in a book form – not distributed.	SOPs were trained, reminders will need to be placed on all notice boards
180	Are all superseded "Master Copies" archived and "Controlled Copies" shredded?				This will be implemented with the next review
181	Are all SOPs available at their point of use?			Not distributed.	Trained will be placed on all the notice boards
182	Are SOPs revised at least once every 2 years?				Will be reviewed going forward
183	Are SOPs practical and suitable?			Not all. Some very important SOPs are missing.	Yes
184	Is the SOPs distribution list appropriate?				Yes to be posted on all notice boards

105	Are there at a minimum SOPs that covers:			
185	 How to create and update an SOP? 			Yes, and trained
186	• Self-inspection (audits)?			Yes, and trained
187	Recall / Withdrawal of medicines from the market?		Need to check – a Mock recall needs to be done to see if they understand how a recall should be done.	Yes, and trained
188	Handling of technical complaints?			
189	Handling of returned goods?			
190	Purchasing procedures?			
191	Receiving / Incoming goods control?			
192	Disposal of rejected materials?			
193	Rodent / Pest control?		Recommend ed	Yes, and trained
194	Handling of counterfeit medicines?		Recommend ed	Yes, and trained
195	Handling of goods in quarantine?		Recommend ed	Yes, and trained
196	 Personal health and hygiene? 		Recommend ed	Yes, and trained
197	 Good housekeeping? Is there an SOP for cleaning of the receiving, storage, packing and dispatch areas in the warehouse as often as needed? 		Recommend ed	Yes, and trained
198	Security of stocks on site / consignments in transit?		Recommend ed	Yes, and trained
199	Training of personnel?		Recommend ed	Yes, and trained
200	Return of defective/non-defective products?			
201	Handling of rejected goods?		NA	
202	• Dispatch?			
203	Cold chain maintenance?		Recommen ded	Yes, and trained
204	Distribution control of SOPs?		NA	
205	Stock rotation / stock control?		Recommen ded	Yes, and trained
206	Handling of scheduled medicines?		Recommen ded	
207	Temperature control of products?		Recommen ded	Yes, and trained
208	Recording of storage conditions?		Recommen ded	Yes, and trained
209	Checking validity of clients?		NA	
210	 Planned preventative maintenance? 		NA	
211	Counterfeit medicines?		Recommen ded	Yes, and trained
	Technical Complaints			
212	Is there a written SOP for handling technical complaints?		NA	Not a focus for CMS at the moment
213	Has the company recently reported a product complaint?			
214	Are technical complaints recorded, followed up and a final report issued?		Recommen ded	
	Recalls			

215	Does the SOP for the recall of medicine include emergency and after hour contact persons and telephone numbers?			Recommen ded	Yes, and trained
216	Does Recalls include a dummy letter that includes name of product, including INN and trade name, strength and pack size, batch number, main therapeutic class, nature of the defect, reason for the recall, date of recall, action to be taken and urgency?			Recommen ded	
217	Is there a separate area for recalled goods awaiting further discussion?			Recommen ded	Yes
218	Is the progress of the recall recorded and a final report issued, including reconciliation between the delivered and recovered quantities of the products?			Recommen ded – Mock Recall needs to be done to make sure everybody understands how to handle a recall of products	
219	Are the Regulatory Authorities of all countries to which products have been distributed, informed?	NA			
	Good house keeping				
220	Is there an SOP for cleaning of the receiving, storage, packing and dispatch areas in the warehouse as often as needed?			Recommen ded – training is also needed.	Yes, and trained
221	Is storage areas kept clean and free from accumulated waste and vermin?			Non existent.	Done
222	Is a written sanitation program (cleaning schedule) for the warehouse available and recorded? Are the cleaning logs available?			To be developed.	Cleaning registers will be implemented, CMS was advised to outsource
223	Are there suitable equipment (Brooms, mops, bins, scoops, etc.) available to carry out effective cleaning routines?			Recommen ded – (got stolen).	Available
	Personal health and hygiene			,	
224	Are pre-employment health checks carried out prior and during employment at regular intervals?			Need to check the labor law.	Not needed
225	Are records kept of all health checks of each employee?			To be developed.	Not needed
226	Are all personnel training in the practices of personal hygiene?			Training needed.	Training done
227	Is the prescribed level of personal hygiene maintained by all persons who come into direct contact with the medicines in the distribution process, whether they are temporary or full-time employees or non-employees e.g. contractors or visitors?				Well maintained
228	Are changing rooms and toilets available?			No changing rooms.	
229	Are changing rooms and toilets separate from the warehouse areas?			Toilets face storage areas directly.	
230	Is smoking, eating, drinking, chewing and keeping plants, food, drink, smoking material and personal medication in the warehouse prohibited?			Some people do eat and drink in the	

			warehouse - discipline is a problem.	
	Pest control			
231	Is there an SOP for pest control and elimination? (rodents, bats, birds, insects and termites)		To be developed and implemente d.	Yes, and trained
232	Is the pest-control agents used safe and registered with the Department of Agriculture for that purpose?			The City of Windhoek will assist
233	Is there a floor plan available, indicating the position of the rodent bait stations?		To be developed.	The City of Windhoek will assist
234	Is there a pest control contract in place with a register service provider?		No pest control spotted.	The City of Windhoek will assist
235	Is the current contract managed?		Managed from Governmen t side – need to check.	Advised to outsource
	Internationally controlled substances			T
236	Are internationally controlled medicines kept?			
237	Are narcotic medicines stored in compliance with International Conventions and National Legislation, Regulations on Narcotic Drugs?			
238	Is there an up-to-date register of all International Controlled medicines purchases and sales, which records: Name and business address of the supplier? Name and business address of the purchaser? Date of each such transaction? Quantities recorded or sold? Balance held in stock at the end of each year?			
239	Are those records kept for at least 5 years after the last date of sale?			
240	Are psychotropic medicines stored in a restricted area and narcotic medicines locked away and keys under control of the pharmacist?			
	Contract activities			
241	Are there signed and valid service level agreements available for: • Pest control?			Was advised
142	 Collection of damaged/rejected pharmaceuticals for destruction? 		In-house	Was advised
243	 For temperature mapping of the warehouse and fridge/cold room? 			Local supplier has a contract with the MoHSS
244	 Security services to prevent theft or tampering with goods? 		Not managed by CMS.	
245	The provision and service fire-fighting equipment?		Not managed by CMS.	
246	 Service delivery trucks, forklifts, hand trucks, cranes, hoists at regular intervals? 		Not managed by CMS.	

247	 Service of air conditioners in the warehouse at regular intervals? 		Not managed by CMS.	
248	 The calibration of temperature recorders/maximum- minimum thermometers in the warehouse, fridges/cool rooms as defined intervals? 		Not managed by CMS.	
	Self-inspection			
249	Is there a written SOP or document driven system for performing regular self-inspection audits?		It will be there after the SCPIP.	Yes
250	Is a self-inspection questionnaire/checklist available?		In process.	Self-inspection checklist available
251	Are these results recorded in an audit report, followed up and the corrective measures implemented?		In process.	Not yet will be done going forward

ANNEX 14: Percentage of functions completed according to SOPs

a) Implementation of Operational SOPs

SOP Reviewed	Implementation
Receiving of	95% SOP implementation
products	 Delivery vehicle register had not been completed (was implemented by the end of the week following this intervention)
	 Non-conformance Product Form was not implemented (a Goods Return to Supplier Form is instead implemented for goods rejected by CMS)
	 It was agreed to introduce a Receiving Checklist and this was designed and piloted by the end of the week.
	 A detailed visual inspection tool was designed for use by the Quality Surveillance Laboratory (located adjacent to CMS) to report on the physical characteristics of products sampled for quality testing. The QSL manager agreed to the target of providing visual inspection results to the Receiving Pharmacist within one day of receiving the samples.
Put away of	84% SOP implementation
products	 Expiry dates need to be listed on the bulk boxes and on the shelving (reinforced and implemented)
	 Need to ensure that the first expiry products are placed in front (reinforced and implemented)
Customer order	• 100% SOP implementation
capture	Order number is used as reference number for an interim order
	 Date of the order will be used as reference number for a main order to link the multiple sales order generated for one customer order. CMS generates multiple sales orders to obtain separate invoices for different categories of products (e.g. cold chain, ARVs, condoms) since some of these products are issued at no cost.
Picking of	• 100% SOP implementation
products	 When the order quantity is less that the minimum case size for CMS, the order quantity is normally adjusted upwards to reflect the minimum case size that is issued. Customers however sometimes order irrationally large quantities and CMS then issues a reasonable quantity based on historical demand but this reflects as inadequate order fulfillment if the order quantity is not adjusted
Packing and	• 90% SOP implementation
Checking	 Dispatch sections not always effective in checking of shipments resulting in some incidents of short-dated or expired products reaching customers.
	 Advised to the various responsible warehouses that each picked product should be delivered in distinct packaging to the Dispatch areas to facilitate checking rather than having many products assembled into pallets when moving to the dispatch for checking. This will allow the Dispatch Pharmacist to do a thorough final check before assembling the shipments ready for transportation. CMS completed maintenance on the pallet shrink wrapping machine and it was in
	working condition
Dispatch of	• 100% SOP implementation
products	Loading of delivery vehicles is often delayed by shortage of workhands (due to absenteeism); only one workhand is permanently assigned to the Dispatch area; it was recommended that additional workhands be assigned to the Dispatch area.

	and the issue of absenteeism be pursued further with the Human Resources at MoHSS HQ.
Transportation of products	• 100% SOP implementation
	 Two new drivers were appointed in November 2014 and are adding huge value to the busy delivery schedule

b) Implementation of Quality SOPs

SOP Reviewed	Implementation
Recall of products	 90% SOP Implementation Most recalls are initiated by the Medicines Regulatory Authority The Distribution Pharmacist implement the recall process at CMS level; Need to review the role of the Chief Pharmacist in the SOP
Handling goods approaching expiry date	 80% Implementation Recommendations were made to fully implement cycle counts to better identify these stock items sooner and avoid dispatching short-dated or expired stock
Effective stock rotation Control of counterfeit and stolen goods	 67% SOP implementation Expiry dates are not checked monthly (cycle counts will be helpful) Shortage of storage space in some warehouses hinders effective stock rotation 0% SOP implementation Vehicles have never been hi jacked
Definition of Roles and responsibilities (Format of Job Descriptions)	 Loss of products is only identified during the stock takes 100% SOP implementation Designed Job Descriptions were re-formatted according to MoHSS HR format with the same level of detail as required by the SOP. Distribution Pharmacist has not yet asked all staff to sign the new JDs apparently due to delays by HR in reviewing the documents The importance of this step was emphasized and it was agreed to have staff sign the JDs immediately since the HR had never objected to this.
Induction and Orientation	 0% SOP implementation Currently new staff will rotate through CMS to get a better understanding of the environment No formal on-boarding process is followed as defined in the SOP Recommendation was made to request that a Human Resources staff member be based at CMS to handle all the staff related issues.
Storage and distribution quality (GDP & GWP)	 80% SOP implementation The general housekeeping at CMS has improved. The warehouses are better organized with all products stored neatly on pallets Cycle counts were recommended but we were advised that the counts could only take place on a Saturday to allow staff to claim over time The temperature logs had not been implemented for general warehouses and this was reinforced. Cold rooms are monitored by an electronic data logging system Shortage of space in the Receiving area and in the warehouses is still a major constraint. Quarantine and Returns areas are marked and used properly at receiving
Self-inspection	0% SOP implementation

and internal audits	This discipline requires dedicated a Quality Assurance staff who will handle issues related to quality audits, corrective actions and SOP revisions.
Corrective actions (In response to client complaints)	 80% SOP implementation Client (facilities/RMS) complaints are listed and acted upon Incidents are not formally investigated and trends are not analyzed to avoid future complaints; The impact of the complaint are not always understood There was however a notable decrease in the number of client complaints partly attributed to better checking at dispatch.
Control of Documents and Format of SOPs	 90% SOP implementation SOPs are updated in correct format but still require approval sign-off Official stamp to be placed on the master copy Official file will be kept with the Distribution Pharmacist SOPs and official documents will need to be reviewed bi-annually
Quality Management systems and Management Reviews	 20% SOP implementation Quality Management file was designed Designated individual will need to be appointed to drive the QMS Quarterly review meetings will need to take place to review the following QMS activities: Assurance of Pharmaceutical product quality Quality Organisation – structure and responsibilities Self-inspections and audits Storage of products Batch definition and lot traceability The control of returned goods Product recalls and customer management Calibration and maintenance of equipment Validation of Cold Chain Computerised system validation Training of staff Management and control of quality critical documentation Control of scheduled drugs Non-Conformance management Product compliant query review and trending

c) Implementation of Health and Safety SOPs

SOP Reviewed	Implementation
Warehouse access and egress control	 16% SOP implementation Security guards are posted at each of the entrances and delivery vehicles are registered Visitors are not required to sign in at reception (recommendation was made) The access control gate into the warehouse is still not operational, CMS has initiated a maintenance request and the gate should be operational within the next 3 months.
Cleaning of the warehouse	 88% SOP implementation The general housekeeping improved Some of the warehouse areas are not so neat and tidy as the rest

Incident and accident reporting	 Recommendation was made to implement a fixed cleaning roster Recommendation was also made to the Chief Pharmacist that CMS should consider outsourcing the weekly cleaning. 17% SOP implementation CMS does not have any trained fire fighters CMS does not have any trained first aiders
	 No investigation or reporting takes place after the occurrence of an incident CMS staff nominated a Health and Safety representative last year but the individual is not active because he has not received relevant training; recommendation made to establish a committee of 2-3 staff and provide them with training as first-aiders and health and safety representatives.
Eating, smoking and drinking in the warehouse	 75% SOP implementation CMS have a dedicated kitchenette separate from the main warehouse facility No eating, drinking or smoking are taking place in the facility CMS needs to install signage at all the main entrances to remind staff and visitors of the restrictions.
Rodent and pest control	 15% SOP implementation There are existing bait stations but they have not been serviced for a long time. Recommendations made to the Chief Pharmacist to contact the City Windhoek, which provides rodent and pest control services.

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