

Republic of Namibia



Ministry of Health and Social Services

**Strengthening the Capacity of the Namibia Medicines Regulatory Council in the Regulation of Antiretroviral Medicines and Other Essential Pharmaceuticals**

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February 2014



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**SIAPS** 



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## **About SIAPS**

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

## **Recommended Citation**

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## **Key Words**

medicine regulation, medicines registration, medicines licensing, capacity building, Good Review Practices, quality testing, Good Manufacturing Practices, GMP, quality laboratory, Good Distribution Practices, GDP, Namibia, NMRC, Namibia Medicines Regulatory Council

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We are grateful for the opportunity to work with such a dynamic and dedicated group.

## ACRONYMS AND ABBREVIATIONS

ADE	adverse drug event
AM	antimalarial
API	Active Pharmaceutical Ingredient
ARV	antiretroviral
ATB	antituberculosis
BP	British Pharmacopoeia
CMS	Central Medical Store
COA	Certificates of Analysis
CTD	Common Technical Document
EML	Essential Medicine List
FDA	Food and Drug Administration
FY	fiscal year
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GRevP	Good Review Practices
HIV	human immunodeficiency virus
HPLC	high-performance liquid chromatography
INN	international nonproprietary name
IT	information technology
MHRA	Medicines and Healthcare Product Regulatory Agency
MoHSS	Ministry of Health and Social Services
MSH	Management Sciences for Health
NAD	Namibian dollar
NCE	new chemical entity
NMRC	Namibia Medicines Regulatory Council
OOS	out-of-specification
PCN	Pharmacy Council of Namibia
PC&I	Pharmaceutical Control and Inspection
PW	purified water
QMS	quality management systems
QSL	quality surveillance laboratory
%RSD	percent residual standard deviation
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SPS	Strengthening Pharmaceutical Systems
SOP	standard operating procedure
SRA	stringent regulatory authority
TB	tuberculosis
TA	technical assistance
TIPC	Therapeutics Information and Pharmacovigilance Centre
UK	United Kingdom
UNAM	University of Namibia
US	United States
USAID	US Agency for International Development
WHO	World Health Organization

## EXECUTIVE SUMMARY

### Background

In 2009, the US Agency for International Development (USAID)-funded Strengthening Pharmaceutical Systems (SPS) Program, implemented by Management Sciences for Health (MSH), conducted an assessment of the NMRC and compiled a report entitled *Strengthening Pharmaceutical Regulatory Capacity in Namibia*.<sup>1</sup> The report described the structure and function of the NMRC, identified challenges in its operations, and provided recommendations for improvements in the NMRC's processes. As part of a five-year strategic plan, several goals were outlined, which included: developing institutional capacity; adopting a risk-based model for registration; streamlining initial screening of dossiers, including bioequivalence evaluations; prioritizing regulatory activities to focus on in-country monitoring; implementing the use of the electronic tool (Pharmadex) for all medicine regulatory activities; developing capacity to cover veterinary, complementary, and biological products; implementing competitive salaries; hiring more technical and administrative staff; revising and updating regulations to address gaps; and implementing capacity building recommendations. Five years following this assessment, the SIAPS Program, which succeeded SPS, provided further technical assistance. SIAPS conducted a holistic follow-up review of the NMRC to establish what progress had been made during the intervening time period, and to reach agreement with the NMRC on how and where SIAPS should focus its attention to strengthen the capacity of the NMRC in the regulation of antiretroviral medicines and other essential pharmaceuticals in Namibia.

### Methodology

Phase 1 of this activity, conducted from January 27 to 31, 2014, involved the review of documents and in-depth discussions with the technical staff of the NMRC Secretariat (see Annex A for the list of NMRC personnel met and interviewed), with the following objectives: to identify goals from the 2009 plan that had been successfully implemented; to gain a better understanding of the roles and responsibilities of the NMRC; and to provide recommendations on how to improve the efficiency of the NMRC's daily operations.

Phase 2, which will be conducted from May 12 to 16, 2014, will involve training members of the NMRC and other interested parties (as determined by NMRC) on Good Review Practices (GRevP), including the Common Technical Document (CTD), Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), and managing the Quality Surveillance Laboratory in a GMP-compliant manner.

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<sup>1</sup> Nwokike, J., D. Lee, E. Sagwa, and J. Gaeseb. 2009. *Consultancy Report: Strengthening Pharmaceutical Regulatory Capacity in Namibia*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

## Findings

Of the 10 goals recommended in the 2009 report, only two were successfully implemented and two were partially implemented. The remaining six goals have not yet been addressed (table 1).

**Table 1. Recommendations from 2009 SPS Report**

<b>Recommendation</b>	<b>Implemented</b>
Develop institutional capacity	No
Implement risk-based model for registration	Yes
Streamline initial dossier screening and bioequivalence evaluation	No
Prioritize activities to focus on in-country monitoring	No
Implement Pharmadex database	Yes
Develop capacity to cover veterinary, biological, and complementary products	No
Implement competitive salaries	No
Hire 7 technical staff to improve capacity	No
Revise regulations to address gaps	Partial
Implement capacity building recommendations	Partial

There are four sections in the NMRC Secretariat that are responsible for the following regulatory functions:

1. **Medicines Registration Section:** Reviews and approves pharmaceutical product dossiers submitted by pharmaceutical companies for market authorizations in Namibia.
2. **Therapeutics Information and Pharmacovigilance Centre (TIPC):** Provides medicines usage warnings and advice to Namibian health care providers, and monitors adverse drug events (ADE) for better patient safety.
3. **Inspection and Licensing:** Oversees GMP inspections and licensing of pharmacies, clinics, hospitals, and wholesalers.
4. **Quality Surveillance Laboratory (QSL):** Analyzes samples of medical products received by the Central Medical Store (CMS) as well as some products received from rural locations in Namibia.

The review of NMRC operations indicates that the chronic shortage of human and technical resources, primarily due to budgetary constraints, have largely contributed to the ineffectiveness of the NMRC in fulfilling its mandate as a medicine regulatory body. For example, the current approved NMRC budget allows for only two pharmacists to be employed full time for medicines dossier review and approval, a key factor explaining the ever-growing backlog of applications. In addition, the budget allows for only two analysts in the QSL, a major factor explaining why samples received often require up to four weeks to analyze. Inadequate human resources, however, was not the only concern raised during the January 2014 visit. Each section had its own limitations, a few of which are outlined below. More details are provided in the main body of this report.

### **Medicines Registration**

- A backlog of over 700 dossiers to be reviewed, some having been backlogged for as long as five years.

### **Therapeutics Information and Pharmacovigilance**

- No information technology (IT) staff are available to provide technical assistance and support.

### **Inspection and Licensing**

- Inappropriate job functions that would be better assigned elsewhere.

### **Quality Surveillance Laboratory**

- Significant violations of World Health Organization (WHO) GMP rendering the QSL essentially ineffective in ensuring the quality of medicines in Namibia.

## **Recommendations**

Given these shortcomings, several recommendations were made to improve the efficiency of the NMRC's operations. Examples of recommendations are:

### **Medicines Registration**

- Until the registration backlog becomes manageable, NMRC should consider “out-of-the-box” strategies for dossier review. These include:
  - Working with the University of Namibia (UNAM) School of Pharmacy to allow final year (fourth year) students, or in the future, post-graduate students and faculty, to spend at least one month as part of their coursework (and earning course credit) learning the basics of medicines registration and assisting in dossier review.
  - Working with the Pharmacy Council of Namibia (PCN), allow an alternate route for pharmacy graduates to become registered with PCN as Namibian pharmacists by spending one year as an intern working with the Medicines Registration Section.

### **Therapeutics Information and Pharmacovigilance**

- Provide better IT support and more staff with expertise in pharmacovigilance.

### ***Inspection and Licensing***

- Consider transferring responsibility for licensing community pharmacies and medicine storage facilities to the PCN and freeing up the GMP inspector to assist with dossier evaluation.
- Prioritize inspection visits to the main port of entry (Windhoek's Hosea Kutako International Airport), where the bulk of medicines enter the country, and visits to the key land crossing customs border posts with South Africa. Work more closely with the headquarters staff of the customs authorities to facilitate the training of their staff at Hosea Kutako International Airport and at the main land crossing with South Africa in the use of PharmaDex.
- Make the Pharmadex database available online thereby allowing Customs and Excise Department staff at all locations to immediately query whether imported products are currently registered with the NMRC.

### ***Quality Surveillance***

- The QSL should strive to become compliant with WHO GMP requirements, otherwise it should cease testing medicinal products.
- QSL staff need to be provided with adequate and effective onsite management, supervision, and training in GMP requirements for product testing.



## INTRODUCTION

National medicines regulatory authorities are intended to ensure the quality, safety, and efficacy of all medicines used in their countries. Their key functions include:

- Licensing of the manufacture, import, export, distribution, promotion, and advertising of medicines
- Assessing the safety, efficacy, and quality of medicines, and issuing marketing authorization
- Inspecting and surveillance of medicines' manufacturers, importers, wholesalers, and dispensers
- Controlling and monitoring the quality of medicines on the market
- Controlling promotion and advertising of medicines
- Monitoring adverse reactions to medicines
- Providing independent information on medicines to professionals and the public

In Namibia, the National Medicines Policy, published in 1998, stipulates the government's aim to ensure that medicines reaching the people of Namibia are safe, efficacious, of good quality, and available at affordable prices. However, Namibia currently faces several challenges in meeting these goals.

The challenges include resource constraints and insufficient funding, ill-defined structures and systems, and limited human resources and skills. Regardless, Namibia's medicines regulation history has seen tremendous improvements and several efforts are being made to develop strategies to further improve the ability of Namibia to safeguard public health and promote the availability of essential medicines for all Namibians.<sup>2</sup>

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<sup>2</sup> Ibid.

## BACKGROUND

The Namibia Medicines Regulatory Council (NMRC) is mandated to regulate and ensure access to medical products and protect public health. To achieve this goal, the NMRC Secretariat, the day-to-day operational arm of the NMRC, requested technical assistance (TA) from the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program funded by USAID to improve and strengthen regulatory capacity on Good Review Practices (GRevP), Good Manufacturing Practices (GMP), quality management systems (QMSs), and post-market surveillance and quality control applicable to pharmaceutical product regulation.

The NMRC Secretariat (referred to in this report as the NMRC) has continued to experience backlogs of pharmaceutical product registration applications as a recurring problem caused primarily by the shortage of skilled manpower. To facilitate timely access to antiretroviral (ARV) and other essential medicines, current TA from SIAPS aims to improve the efficiency of the NMRC and consequently, reduce the average number of days taken to evaluate and approve applications for the registration of medicines by providing training on pharmaceutical dossier evaluation. As such, SIAPS is collaborating with the NMRC to develop practical regulatory guidelines and use them to train staff to strengthen their capacity for evaluation of registration dossiers and to conduct inspections, including GMP inspections and post-marketing surveillance activities. SIAPS is also supporting the NMRC to review the strategy document developed in 2009 under the SPS program to assess progress made in addressing identified priorities, and to develop guidelines on emerging regulatory topics that will support the NMRC to achieve its mandate.

These interventions will contribute to strengthening the capacity of pharmaceutical regulatory personnel to improve the process for registration of pharmaceuticals, and will ensure improved access and use of quality, safe, and efficacious ARVs, essential medicines, and other pharmaceutical products in Namibia.

### NMRC Mandate and Structure

The NMRC is mandated to perform the functions assigned to it by the Namibian Medicines and Related Substances and Control Act of 2003, which requires that the NMRC ensure the quality, safety, and effectiveness of medicines in Namibia. The 12-member council is made up of health care professionals, including physicians, pharmacists, registered nurses, veterinarians, legal practitioners, and others. Currently, in the Ministry of Health and Social Services (MoHSS), the Pharmaceutical Control and Inspection (PC&I) is the secretariat of the NMRC. PC&I is a subdivision of the Pharmaceutical Services Division that is under the Tertiary Health Care and Clinical Support Services Directorate. The PC&I Secretariat, whose head is the Registrar of Medicines, also has responsibility for implementing the NMRC's decisions. The role of the Registrar of Medicine as the secretary of the NMRC is spelled out in the 2003 Act. However, apart from the description of the procedures of meetings of the NMRC, Executive, and Veterinarian committees, the Act does not specify in detail the functions, roles, and responsibilities of other committees. Other committees appointed by the NMRC include the Pharmaceutical and Analytical, Legal, and Clinical Committees.<sup>3</sup>

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<sup>3</sup> Ibid.

## METHODOLOGY

The goal of this activity was to strengthen the institutional capacity of the NMRC Secretariat's regulatory medicines approval system, its facility GMP inspection capabilities, and the operations of NMRC's Quality Surveillance Laboratory (QSL) with respect to the registration and handling of medicines used for human immunodeficiency virus (HIV), tuberculosis (TB), malaria, and other essential pharmaceutical products, as well as improve the process for pre- and post-marketing surveillance activities.

The original scope of work involved the development and implementation of regulatory guidelines for GRevP, GMP, quality management systems (QMS), and Common Technical Document (CTD) followed by training on these guidelines. However, before the guidelines could be developed, it was important to understand the current pharmaceutical regulatory status and processes in Namibia. The following tasks were therefore implemented:

### **Phase 1 (January 24–31, 2014): Review of the Current Functioning of the NMRC**

A review was conducted on how the NMRC operates. Potential solutions were proposed for some areas where the NMRC may need to improve. The assessment was done through the review of documents, including existing standard operating procedures (SOP), job descriptions, and quarterly reports, and in-depth discussions with NMRC staff members (Annex A). Visits were made to the NMRC Secretariat to review available manual and electronic databases. NMRC Secretariat staff provided additional input during consultative meetings scheduled specifically to obtain feedback on the functioning of each unit of the NMRC Secretariat.

### **Phase 2 (May 12–16, 2014): Training NMRC Staff on Regulatory Guidelines**

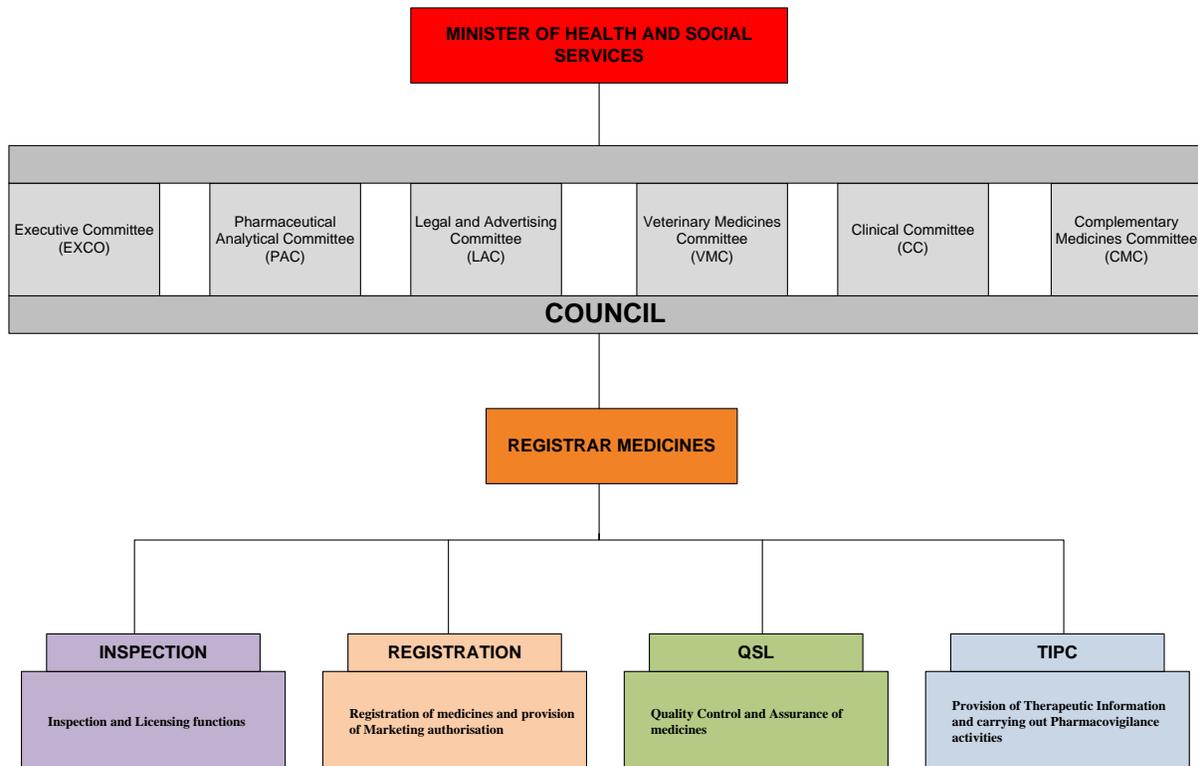
Phase 2 will consist of capacity building (training) activities on the registration, inspection, and testing of ARV, antituberculosis (ATB), and antimalarial (AM) medications. By providing opportunities to enhance the registration and GMP compliance of ARV/ATB/AM medicines, the registration and testing of other medications in Namibia will also be strengthened.

The capacity building efforts will focus on:

- Understanding the role and function of electronic-CTD in improving the NMRC registration process, and gaining an understanding of how to efficiently evaluate registration dossiers.
- Providing knowledge on current expectations for the performance of GMP inspections of pharmaceutical manufacturers.
- Providing knowledge on current expectations for the performance of Good Distribution Practices (GDP) inspections as they relate to distribution centers (including the Namibian Central Medical Store [CMS]), wholesalers, and the remainder of the downstream supply chain.
- Providing knowledge on current expectations for the performance of the QSL to the standards and expectations of WHO's GMP and QMS as they apply to the QSL function.

## FINDINGS

As seen in figure 1, the NMRC Secretariat consists of four sections (functional units) responsible for the registration of pharmaceutical products, the inspection and licensing of health facilities, quality surveillance, and therapeutic information and pharmacovigilance.



**Figure 1. Organizational structure of the NMRC**

The review of the NMRC Secretariat's activities identified the need for improvements in several areas.

### **General Considerations Concerning the Efficiency of NMRC Operations**

- Current staffing levels at the NMRC are grossly inadequate to provide proper services in accordance with the NMRC's mandate. Staffing shortages are due to three factors:
  - Staff positions need to be approved by the MoHSS Public Service Commission in the Office of the Prime Minister, which strictly controls the NMRC headcount and budget.

- Salaries paid to NMRC staff for pharmacist positions are not competitive. A pharmacist can earn two to three times more salary in the Namibian private sector.
- Almost all staff positions are restricted to registered pharmacists, including the reviewers in the Registration department and staff in the Inspection and Licensing department. The pool of available potential candidates for these positions is therefore limited. Rather than restricting the position of medicines dossier reviewer to registered pharmacists, NMRC would be better served if the position was open to graduates with a biology-based or health care-related degrees.
- NMRC fees for the registration of a medicine in Namibia were arbitrarily established in 2009, set to be similar to fees charged by other countries in Southern Africa (including Botswana, Lesotho, Zambia, and Zimbabwe). They are not realistic and do not cover the true costs of the registration process in Namibia. The current fees charged do not come close to covering the salary of the NMRC reviewer for the time s/he spends performing a dossier review.
- Applicants for medicines registration do not receive routine or transparent feedback as to their position in the registration review queue. They do not know whether their products are scheduled for rapid, accelerated review (i.e., essential medicines, ARVs, ATB and AM medicines), or are at the back of a 700-dossier backlog (as of January 2014). At the present rate of dossier review—about one dossier reviewed per reviewer per week—it will take approximately 14 years to clear the dossier review backlog. This is without new dossiers being added to the backlog at a rate of about 100 per year. The medicines dossier review rate could be increased, and the rate of growth of the backlog slowed, with implementation of the web-based version of Pharmadex later in 2014.
- The NMRC is unable to determine how many medicines dossiers received are new registration dossiers, or are changes to existing dossiers.
- The NMRC does not have a system for succession planning. Current position holders in the Registration, Licensing and Inspection, QSL, and TIPC Sections are either senior staff close to retirement, or are non-Namibians on fixed contracts that need to be renewed. The Namibian government has a policy of trying to appoint Namibians to all civil service positions, making it questionable as to whether the NMRC's current non-Namibian staff will have their contracts renewed.
- While metrics exist to measure departmental progress and accomplishments of the NMRC Secretariat, quarterly reports provided by the departments to the NMRC Registrar (the senior staff member of the NMRC Secretariat) are inconsistently prepared. Moreover, their content makes it difficult to assess progress against established metrics, for example, to accurately discern how many dossiers are in the backlog, or how many samples have yet to be tested by the QSL (Annexes B, C, and D).
- The NMRC has many SOPs describing how tasks are to be performed, but there is no formal link between job descriptions and the SOPs, nor how a new job holder should be trained to

satisfactorily perform his/her job functions. Moreover, all of the SOPs made available to and reviewed by the SIAPS team are in draft form. They still need to be reviewed and approved by the QSL and NMRC senior management to become official departmental policies and procedures, and to be used to train staff.

- Where they exist, the NMRC SOPs do not appear to be used by staff on a regular basis, either by the Medicines Registration and Licensing and Inspection Sections or by the QSL.
- There appears to be poor supervision of the QSL by senior management. The problems described below would not have emerged otherwise. The imminent move of the QSL from its current location in Windhoek to a new location, together with the planned move of the CMS about 80 km away, may exacerbate the NMRC's ability to effectively manage the QSL.

### **Medicines Registration Section**

Following discussions with the two pharmacists responsible for the registration of medicines in Namibia, the following points were observed:

The Section's function is to review registration dossiers submitted by the global pharmaceutical industry and to provide compassionate clearance certification for medications required by physicians for "named patients" whose medication is not otherwise registered and available in Namibia.

In fiscal year (FY) 2013, the Section reviewed about 200 dossiers. It has a backlog of over 700 dossiers to be reviewed, some more than five years old. With the exception of ARVs, TB medicines, and AMs, medications that the CMS advises are "urgently needed," all dossiers are reviewed on a first-come-first-reviewed basis. There does not appear to be a written procedure or flow chart guiding the order in which dossiers are to be reviewed.

### **Therapeutics Information and Pharmacovigilance Centre (TIPC)**

The TIPC Section is staffed by one medical officer. TIPC provides medicines usage warnings and advice to Namibian health care providers by issuing the quarterly Namibian Medicines Watch. It also monitors adverse drug events (ADE) in Namibia. It received approximately 100 ADEs during FY2013. The TIPC also:

- Responds to medicines queries from Namibian practitioners
- Conducts targeted active surveillance, e.g., clinical monitoring of the safety of ARVs
- Provides training for regional health facilities on pharmacovigilance

The TIPC currently devotes about 50% of its time to therapeutic information activities and 50% of its time to pharmacovigilance activities. When a serious ADE is reported, the information is submitted to the Clinical Committee of the NMRC, which determines whether the ADE warrants the sending of notifications to physicians throughout Namibia. There is no SOP describing how

this deliberation and notification process works. ADEs are recorded in the Vigiflow software database. There are currently no personnel trained and/or available to review the database and make recommendations from the data collected, apart from the TIPC medical officer.

### **GMP Inspection Section**

There is only one NMRC pharmacist responsible for GMP inspections and licensing of pharmacies, clinics, hospitals, and wholesalers in Namibia. In FY2013, he performed one GMP inspection of a local Namibian manufacturing facility, and no inspections of overseas facilities that export medicines to Namibia. Moreover, in FY2013, 158 inspections were performed of other Namibian in-country facilities where medicines are stored, including pharmacies, physicians' offices, and rural clinics. The pharmaceutical inspector also liaises with customs officials to ensure that they are knowledgeable about medicines banned for importation and use in Namibia.

### **Quality Surveillance Laboratory**

The head of the QSL is a pharmaceutical chemist, who is assisted by two analytical staff and one assistant. In FY2013, the QSL staff analyzed 161 samples. Based on our observations, the QSL does not meet minimum requirements for GMP compliance nor WHO guidelines to qualify as a medicines testing laboratory.

The QSL primarily analyzes samples of medicine products received by the CMS as well as products received by both private and public sector facilities throughout the country. The QSL's objective is to test medicines to assure that those distributed in Namibia meet their specification requirements as to potency and purity. In most countries, products that have been sampled for testing are held in quarantine and are not distributed until the test results have shown that the product meets the specifications. This does not happen at the Namibian CMS. The CMS does not quarantine any incoming medicine; medicines are distributed on a first-in-first-expired basis, regardless of whether or not they have been sampled, and regardless of whether the QSL has completed its testing of the products.

The time required sampling a product for testing, scheduling the testing, and reporting results typically takes up to four months. If a sample is found to be out-of-specification, it is sent to a WHO-qualified independent South African laboratory for confirmatory retesting. It can take up to another two and one-half months to obtain a result from this independent laboratory. Six and one-half months are therefore needed to positively state that a product does not meet a specification, by which time the medicine has in all likelihood passed through the entirety of the downstream supply chain, and has been used by patients.

A cursory review of the facility during the SIAPS team's one-hour visit to the QSL showed several significant violations of GMP for pharmaceutical quality control laboratories as regards the manner in which the laboratory operated and compliance with the requirements of ISO 17025, "*General requirements for the competence of testing and calibration laboratories.*"

The deficiencies identified included:

- About one-third of the samples awaiting testing had exceeded their expiration dates, making testing moot.
- Equipment was observed operating with expired calibration dates.
- Eight reagents and indicators were past the expiry dates indicated on their labels and no action had been taken by the QSL.
- Laboratory standards (e.g., the Isoniazid international chemical reference standard being used in a test ongoing during the visit) was stored incorrectly (at room temperature rather than being refrigerated), and was stored with its cap loose such that humidity and airborne contamination might impact its use as an official standard. Moreover, there was no documentation that the standard had been dried at 105°C for four hours as required by the USP immediately prior to use in the ongoing test to ensure that the product being tested met the Isoniazid USP reference standard specification.
- The storage and handling of the Isoniazid standard was not in accordance with the QSL's own procedure, "*Maintenance of Reference Standards and Materials*" (NMRC/QSL/3015/1).
- While the QSL has an in-house reference standard for Isoniazid, it was stated as being "not as pure as the WHO International Chemical Reference Standard." The in-house standard is not used for testing products, which belies the purpose of having in-house standards.
- Purified water (PW) used in testing products is generated from a Millipore Elix system that has lights indicating the equipment's condition. The "alarm" and "servicing" lights were observed in a lit condition. The SIAPS team was advised that the device had been in this condition for about six months due to lack of parts and funds for maintenance.
- The log sheet for the conductivity of the PW generated last showed an entry for July 17, 2013, and at that time the entry was 5.7 MΩ, equivalent to 0.18 μS/cm<sup>2</sup> and was within British Pharmacopoeia specification. However, there is no documentation of the water quality used on the date of the visit, six months after the last reading, and its suitability for use in ongoing testing. This is of particular concern as the device generating the PW (the Millipore Elix system) had lit lights advising that servicing was required, and that the device was in alarm condition, as noted above.
- The manner in which test results are computed is not in accordance with WHO GMP requirements (section 17.13). A test sheet for testing a batch of quinine showed that three results had been averaged to obtain a final test result. Two of the three individual test results were observed to be out of specification, while the third result was in specification. When these three results were averaged, the average result was within specification and the product was approved (Annex G). The percent residual standard deviation (%RSD) of these results has not been compared to the %RSD specification.

WHO, US Food and Drug Administration (FDA), UK Medicines and Healthcare Product Regulatory Agency (MHRA) and Pharmaceutical Inspection Cooperation Scheme member states (including South Africa) have guidelines on how to handle out-of-specification (OOS) test results. They do not allow the averaging of test results without an investigation as to whether the individual OOS test results are due to laboratory error or to the product itself. No such investigation has been documented for this tested batch.

The QSL has its own procedure on Handling Non-Conforming Test Results (NMRC/ QSL/3006/1), which requires an investigation to be performed. However, the SOP provides no guidance along the lines of that provided by WHO and stringent regulatory authority (SRA) countries.

- There is no documentation that the spreadsheet used to average the test results noted above has been validated.
- Although medicines being tested need to conform to current pharmacopoeia standards, the latest available edition of the British Pharmacopoeia (BP), one of the pharmacopoeias officially recognized in Namibia, is the 2009 edition, not the current 2013 version (current at the time of the visit to QSL). There have been significant revisions to BP specifications and requirements over the last five years.
- The manner in which ongoing testing is documented is not in accordance with GMP requirements to extemporaneously record testing activities. Moreover, not all activities performed are documented.
- There is no documented evidence that the chromatography columns used in high-performance liquid chromatography (HPLC) testing are restricted for use for single test substances, or that the columns have been adequately cleaned between analyses of different substances. Nor was there documented evidence that the HPLC being used during the visit had passed its system suitability testing to prove that the HPLC equipment had been assembled and set up correctly in a manner that would generate accurate test results.
- Laboratory glassware is hand washed. There was no documented evidence that the hand washing of glassware conformed to a validated washing process and provided acceptably clean glass for use in further testing.
- There was no documented evidence that analytical staff had been trained in QSL SOPs on how to document test results, operate equipment, perform tests, and work in a GMP-compliant manner.
- The SOPs used in the laboratory were all marked as effective July 2012 and were due for review in 2014. However, none of the SOPs appeared to have been reviewed and approved by senior management, and all SOPs reviewed indicated in a watermark that they were in draft.

- There seemed to be poor and infrequent senior management oversight of the QSL function. The QSL reports to the chief pharmacist, whose job description and prior on-the-job training did not appear to include managing the QSL function in a GMP-compliant manner.

As part of the possible relocation of the CMS scheduled for late 2014 to a town about 80 km outside of Windhoek, it is planned that the QSL will also move to be adjacent to the CMS. It is feared that this move will render NMRC management oversight even less frequent and less effective. It is also feared that current QSL staff will not, for personal and economic reasons, remain with the QSL at its new location. It is likewise of concern that the QSL will have great difficulty hiring and retaining suitably trained and motivated staff at a new facility if it is located outside Windhoek.

At the request of the QSL Manager, the proposed design plan (layout) of the new QSL facilities was reviewed. Several key GMP compliance deficiencies and operational inefficiencies were noted in the plan (Annex H). To ensure that the new QSL facility operates properly, these deficiencies need to be rectified prior to the start of construction. This information was relayed to the NMRC/QSL.

The proposed layout of the new QSL facility consists of a chemistry lab, a microbiological testing laboratory, and a condom physical testing laboratory. The QSL has been advised that the operation of a microbiology testing laboratory is a far more challenging task than required for operating a chemical testing laboratory. If the QSL were to operate the proposed new microbiological testing facility in the same manner that it currently manages and operates its chemical testing laboratory, there is serious reason to believe that microbiological testing would frequently result in tests showing failure (i.e., positive bacterial growth) due to the QSL's current laboratory handling and laboratory design issues and the need for samples to be tested independently in accordance with QSL policies, a cost and logistics nightmare for the QSL.

The QSL's work is closely linked with the work of the CMS, from which it receives samples of medicines to be tested. While the QSL is officially supposed to take the medicine samples, this task has been relegated to the CMS, where a CMS pharmacist takes samples and sends them to the QSL. If the pharmacist is absent due to sickness or vacation, for example, no samples are taken. CMS employs several pharmacists on two-year assignments from Cuba. Due to their very limited knowledge of English, they have difficulty performing their job functions, which appear to primarily be as storekeepers.

In the event that the pharmacist assigned to take samples is absent, no other CMS pharmacists are reassigned to fill this temporary void, nor is any other CMS staff member (a non-pharmacist) trained to take samples. For the period Christmas 2013 until the end of January 2014, the pharmacist assigned to take samples was on vacation, and no shipments received by CMS during that period were sampled.

Because the QSL itself does not take samples from incoming shipments, there is no practical reason why the QSL needs to be relocated to be adjacent or in close proximity to the CMS. It is therefore strongly recommended that the QSL physically remain in its current Windhoek location.

## DISCUSSION

### General Considerations Concerning the Efficiency of the NMRC's Operations

As previously mentioned, the shortage of staff is a major problem at the NMRC, due in large part to positions that are deemed suitable only for pharmacists, which are lacking in Namibia. In many other national regulatory agencies (including the US FDA, the UK MHRA, and the European Union), such positions are not restricted to pharmacists (Annex F). Recruitment of staff is impacted because the official position of “pharmacist” has a different pay scale in the MoHSS system (and indeed in the entire government system) than other qualified professionals, such as biologist or chemist, who are considered capable of holding the position of medicines dossier reviewer or GMP inspector in other countries.

The fees to register medicines in Namibia have been arbitrarily assigned based on similar fees in adjacent countries. The current NMRC medicines registration fee is 1,750 Namibian dollars (NAD) for a generic medicine and 3,500 NAD for a new chemical entity (NCE). Generic medicines constitute the bulk of products registered by the NMRC. According to the NMRC job descriptions (Annex E), a pharmacist receives an annual salary of 248,284 to 296,663 NAD (equivalent to about 22,000 to 27,000 US dollars), with the average annual salary for a NMRC pharmacist being 272,473 NAD, equivalent to 5,239 NAD per week. It typically takes one week to review a generic medicine application received from a non-SRA country, meaning that the cost for the dossier review, in simple salary terms (not including department overhead, such as staff benefits, external staff training, computer system and software, etc.) is a money-losing proposition. The generic medicine registration fee paid by the applicant covers only one-quarter of the salary required to review the application. In other words, the NMRC is losing a significant amount of money for each medicines dossier it reviews—about 3,500 NAD per dossier—or 700,000 NAD for the 200 dossiers reviewed during FY2013.

Registration fees and annual licensing fees need to be set such that they support sufficient manpower at the NMRC Secretariat. This will improve efficiency and allow companies registering products a definitive registration decision within a reasonable time period, say 12 months from the date of acknowledgement of the registration application. A key way that this objective may be achieved is for the NMRC to become a self-funding agency within the MoHSS, which is highly recommended.

### Medicines Registration Section

The backlog of product dossiers continues to plague the Medicines Registration Section of the NMRC. There are simply not enough human resources to review all the applications in a timely manner. With the assistance of “retreats” using regional pharmacists, the three staff pharmacists reviewed about 200 registration dossiers during FY2013, but about 300 new registrations dossiers were received during this same period. Thus, the “backlog mountain” has grown at a rate of about 100 registration dossiers annually. NMRC registration pharmacists advised that

many of the dossiers in the backlog are from the fourth, fifth, or sixth applicant for a generic product already registered.

The registration staff have started to use Pharmadex to help expedite the review process. However, the process suffers from several deficiencies that are expected to be resolved with the imminent installation of a web-based version of Pharmadex. The current registration system deficiencies include:

- NMRC technical staff are required to act as clerks, physically filing and retrieving dossiers from the dossier storage area because all dossiers are currently received in hard copy format.
- NMRC technical staff are required to enter the administrative details of the registration dossier into Pharmadex themselves, which takes significant time away from reviewing the scientific and technical merits of the dossier.
- The NMRC computers used by the three registration pharmacists are not linked to a central database, making the review process inefficient because staff cannot collaborate on the review of a dossier. This problem is expected to be resolved with the new online version of Pharmadex.

The NMRC has implemented a risk management review process under which dossiers from SRA countries are given an accelerated review of about one-half day, and dossiers from non-SRA countries are reviewed in about five days. In an effort to diminish some of the backlogged dossiers, retreats are organized during which the entire NMRC office shuts down and all efforts are focused on reviewing backlogged dossiers. During the last retreat in January 2014, about 50 dossiers were reviewed.

Although the NMRC has a series of SOPs to guide it in handling the review of dossiers, they do not appear to be readily available to staff. For example, there is no documented evidence that a young pharmacist, the newest recruit to the Medicines Registration Section and working in the department for about eight months, has been trained in any of the departmental SOPs relating to dossier review. The pharmacist stated that her training typically involved watching how the head of the Medicines Registration Section performed his duties.

### **Therapeutics Information and Pharmacovigilance Centre**

The TIPC Section is hindered in its work because there are no information technology (IT) staff available to provide IT assistance. For example, concerning the relatively simple matter of relocating the TIPC telefax machine (which receives the ADE reports) from its current location in an office in the Windhoek Central Hospital to the TIPC office at the NMRC headquarters, there is no IT support for the relocation. Relocation of the telefax machine would improve the TIPC's efficiency by eliminating a lengthy and time-consuming walk to check for faxes and retrieve any faxes received.

## **Inspection and Licensing**

Part of the NMRC Inspector's function as the GMP Inspection and Licensing Pharmacist is to audit pharmacies, clinics, hospitals, and wholesalers to determine whether they store medicines in accordance with regulatory requirements. This is a remnant of an old British practice—that locations handling and/or storing medicines need to be licensed and inspected. In almost all Commonwealth countries, including the United Kingdom (Pharmaceutical Society), Ghana (Pharmacy Council), Kenya (Pharmacy and Poisons Board), Nigeria (Pharmacists Council), and South Africa (Pharmacy Council) as well as in the United States (State Boards of Pharmacy), the inspection of pharmacies, clinics, and other locations where medications are stored is not a regulatory agency function, but it delegated to the country's professional Pharmacy Bodies. Regulatory agencies concentrate on inspecting manufacturing facilities for GMP, a skill that is irrelevant to the storage of medications.

## **Quality Surveillance Laboratory**

Based on our observations, the QSL does not meet the minimum requirements of the WHO's GMP guidelines for Pharmaceuticals Quality Control Laboratories, or the requirements of ISO 17025 "*General requirements for the competence of testing and calibration laboratories*" to qualify as a medicines testing laboratory. As it currently operates, the QSL provides Namibia with no value added as a testing laboratory to determine the quality of medicines imported and distributed in Namibia.

## RECOMMENDATIONS

The following recommendations are made based on the review of NMRC activities. None of these recommendations are stand-alone cures for the deficiencies noted. However, taken together and if implemented wholly or partially, they may bring about significant improvements in the efficiency of current NMRC operations.

It is realized that implementation of some of the recommendations involves discussions with other Namibian agencies, for example:

- The Pharmacy Council of Namibia (PCN), part of the Health Professions Council of Namibia, for changing the responsibility to inspect pharmacies and physicians offices from the NMRC to the PCN.
- The need to publish in the “Namibian Government Official Gazette” the proposed changing of the fee structure for registration of medicines in Namibia.
- Cooperation with the University of Namibia (UNAM), School of Pharmacy to allow final year students to perform internships of at least a six-month duration at the NMRC.

### Findings and Recommendations for Corrective Action

#### ***Medicines Registration Section: Staff shortages and tackling the backlog in the review of the medicines registration dossiers***

- The NMRC needs to become a self-funding agency within the MoHSS. Funds raised from medicines licensing and other fees may be used to cover the costs of running the department with a more adequate number of staff.
- The NMRC needs to establish a registration and annual license fee structure to cover its total costs, including salary, benefits, travel, office expenses, etc.
- Medicines registration fees should be paid in one upfront payment prior to the commencement of the review of the dossier, and should include:
  - A screening fee to ensure that the submission is complete
  - A fee to review the dossier
  - A license fee for the first year’s license

It is recommended that if the dossier fails the review process:

- At the initial screening, and if supplemental information is required from the applicant, only half of the fees paid are refunded, and the dossier will need to be resubmitted in full with payment of the full registration fee.

- In the in-depth review due to missing, incorrect, or fraudulent data, no fees will be refunded.

These recommendations are made to place the onus on the applicant to ensure that the submitted dossier is “right the first time” and to minimize the workload placed on the NMRC.

- The NMRC will continue to face a chronic staff shortage if it continues to restrict dossier review to “pharmacists.” It needs to change the function/position requirements to allow university graduates in life-science disciplines, such as biology and chemistry, to be trained in medicines regulatory affairs. This recommendation also applies to restricting GMP inspections to be performed by pharmacists only.

This change will impact NMRC salaries as “pharmacists” are on a different salary track than “biologists,” for example. Salary tracks need to be based on the function requirements of the position, rather than on the qualifications of the position holders.

- The NMRC will find it advantageous to encourage and fund suitable non-pharmacist (and pharmacist) entrants into the department to obtain masters’ degrees in regulatory affairs by distance learning methods (e.g., Internet courses available from Northwestern University or San Diego State University in the United States, and other schools). These courses are not taught in pharmacy schools nor are the key skills that dossier registration reviewers need to have to effectively perform their job functions taught in pharmacy schools.
- Until the registration backlog is brought under control, the NMRC should work with the College of Pharmacy to allow final year (fourth year) students to spend at least a month as part of their coursework (and earning course credit) learning the basics of medicines registration and assisting in dossier review.

UNAM pharmacy students are currently provided with a two to three day introduction to the department, but this yields no practical benefit to the NMRC or pragmatically to the pharmacy student.

- Work with the PCN to allow pharmacy graduates to become registered with the PCN as Namibian pharmacists by spending at least six months working as an intern in the Medicines Registration Section.
- Work with the CMS to ensure that instead of publicizing open bids for medicines supply, CMS includes in their bidding documents a requirement that only suppliers whose medicines are already registered with the NMRC may supply that medication as part of the CMS bid. Moreover, bids should only be from finished dosage forms that have been inspected in the previous two years for GMP compliance by an SRA or by the WHO through its Medicine Prequalification Programme, and whose active pharmaceutical ingredient (API) of the finished dosage form has been manufactured at a facility inspected in the previous two years for GMP compliance by an SRA or through the WHO Prequalification Programme.

- Provide training in GRevP and effective assessment of pharmaceutical products registration dossiers. This will be addressed in Phase 2 of the current assignment.

### **Bringing Efficiency and Transparency to the Medicines Dossier Review Process**

- Rapidly implement the web-based Pharmadex to allow the NMRC to gain efficiency by having applicants enter the administrative details of their application.
- When the web-based Pharmadex goes live, through publication in the Namibian Official Gazette (and via e-mail to existing applicants), advise the public inside and outside Namibia and all applicants of all pending medicines registration dossiers that:
  - Effective *<insert date>*, all applications for registration of medicines in Namibia need to be in CTD format and submitted via the web-based Pharmadex system, including the uploading of the dossier in electronic format (either as a Word document or as a PDF file).
  - Advise applicants that effective *<insert date (same as above)>*, a new fee structure will be implemented for new dossier applications.
  - For applicants with existing applications waiting for review, advise them of the need by *<insert date (same as above)>* to complete the administrative section of their applications via the web-based Pharmadex, and upload their existing dossiers in electronic format (either as a Word document or as a PDF file). Also advise them that until these actions are performed, their dossiers will not be reviewed.
  - Advise applicants of registration dossiers that they may obtain a list of all medicines currently registered with the NMRC via the web-based Pharmadex, including the international nonproprietary name (INN) and the applicant's name and address. They may also see when they can expect to have their application dossier review completed (in accordance with a publicly published prioritization for dossier review – *see point below*).
- Publish an official NMRC policy that medicines registration dossiers will only be accepted for finished pharmaceutical dosage forms that:
  - Have been manufactured in Namibia in accordance with WHO GMPs, and have passed inspection by the NMRC, or
  - Where the specific dosage form being registered has itself been inspected at its site of manufacture in the previous two years for GMP compliance by an SRA or by WHO through its Medicine Prequalification Programme, and whose API of the finished dosage form has been manufactured at a facility inspected in the previous two years for GMP compliance by an SRA or through the WHO Prequalification Programme.

A copy of the detailed SRA/WHO inspection report must accompany the registration dossier.

- Applicants must provide an annual product quality review to the NMRC to allow it to monitor ongoing product quality, and to plan potential site inspections for GMP compliance.
- Publish an official NMRC document (to be made available on the NMRC website as well as in the *Namibian Official Gazette*) describing the prioritization of medicines registration dossiers review. It is recommended that dossier review prioritization follow the following sequence:

First priority: ARV/ATB/AM medications, and other medications providing a significant therapeutic advantage to patients where no alternate therapy exists in Namibia. This would include “compassionate requests” from physicians.

Second priority: medications on the essential medicines list (EML), where not more than one other generic version of the INN product is already registered for that dosage form.

Lowest priority: other generic dosage forms, where more than two generic versions of the dosage form are already registered with NMRC for distribution in Namibia.

- The current NMRC website has many links that do not work and has not been updated for several years. It is urgent that the NMRC website, a key tool in ensuring the agency’s transparency, be working effectively to provide answers to stakeholder questions.

## **Therapeutic Information and Pharmacovigilance**

Provide IT support, as discussed above in the Findings section of this report.

## **GMP Inspection and Licensing**

The following recommendations are made to free up the skills and talents of a pharmacist from this section so that s/he may be more effectively used in the Medicines Registration Section.

As previously mentioned, it is suggested that “compassionate release” is a Medicines Registration issue, and that the issuance of “compassionate release” permits for named patients may be handled more effectively than at present. Two possible options exist to streamline “compassionate release” certification. Either:

- Allow a Namibian physician’s prescription to be the certification needed by the importer or distributor to bring the medication into the country (a practice used in Canada, Europe, the United States, and other countries); or
- Have the Medicines Registration Section handle this activity as part of its registration function.

It is suggested that the NMRC negotiate with the PCN that this function, and the fees that are derived from these inspections, be transferred to the PCN for their control and supervision. It is recognized that this recommendation may require changes to the Namibia Medicines Control and Related Substances Act, but its implementation will relieve the NMRC of work that it is not equipped to handle.

It is recommended that the NMRC, working with the CMS, require that all medicinal products imported into Namibia enter through Windhoek Airport and the main land border crossing to South Africa, and that Namibia Customs and Excise staff at Windhoek Airport and the main land border crossing to South Africa have real time access to Pharmadex, allowing customs staff the ability to check in real time whether a medication is registered with the NMRC.

A direct link should be established from the Customs and Excise Department of the Namibian Ministry of Finance to the Pharmadex database so that it can immediately and continuously check on whether imported medicines are properly registered with the NMRC.

The NMRC is unusual in that it requires a “pharmacist” to perform the function of a GMP inspector. The US FDA, the UK MHRA, and the GMP inspectorates of other SRAs do not require their medicines dossier reviewers or GMP inspectors to be qualified pharmacists (Annex F). In fact, pharmacy education is tending more towards being patient-oriented and meeting the needs of clinical pharmacy. Very little education in pharmaceutical manufacturing and quality control and testing are part of a pharmacist’s education. Training in medicines registration activities is not part of the curriculum and is not taught. It is recommended that the NMRC widen the scope of those permitted to become a GMP inspector to university graduates with a science degree who have worked in a management position in the pharmaceutical manufacturing industry.

### **Quality Surveillance Laboratory**

- Until such time as the QSL is in compliance with WHO GMP requirements, as inspected by a third party inspection agency, or can be certified as compliant with ISO 17025 standards, *it is recommended that the QSL consider suspending all testing of medicinal products.*

If the recommendation provided above to only source medicinal products from SRA inspected manufacturers is accepted, then the Namibian population is at no greater risk than that faced under the current system where product testing cannot be assured to provide a correct test result and where, if a product is deemed to have failed testing, there is a high likelihood that it has already been consumed by patients by the time that the test results are known.

- If the NMRC wants to eventually operate the QSL as a sound, trustworthy laboratory, then QSL staff need to be provided with adequate and effective onsite management, supervision, and training in the GMP requirements for product testing laboratories. All test methods need to be validated/verified, and all analysts need to be properly certified as to their capabilities.

- Sampling of products received from the CMS is currently an after-the-fact effort to assure pharmaceutical quality. If the NMRC is determined to test products in the QSL, it would be better if this testing were performed during the dossier review phase. To do this, applicants need to be required to provide finished dosage form samples in original packaging from three samples from different consecutive product batches whose batch records are being submitted in the dossier. These three samples would be tested for compliance to product specification.

Moreover, Certificates of Analysis (COA) for the prior thirty consecutive batches of the product submitted in the registration dossier should be provided to allow QSL staff to perform calculations of process capability for product yield, potency, and impurities. Evidence of acceptable process capability (a process with a process capability index (Cpk) > 1.3) provides assurance of the dossier applicant's process robustness. These COAs obviously will not be from products sold in Namibia, but the COAs need to come from batches of products manufactured on the same equipment at the manufacturing site stated in the dossier.

- In order to enhance management and supervision of the QSL when it gains WHO or ISO 17025 approval, it is essential that the QSL facilities be located in Windhoek. Moving the QSL facilities, together with the CMS, to a location 80 km away from Windhoek is not recommended because:
  - Current staff will probably not move to the new facility for personal, social, and economic reasons.
  - It will be difficult to recruit qualified new staff to work at the facility.
  - Supervision by senior NMRC staff would be greatly compromised. As such, the QSL would suffer from an “out-of-sight, out-of-mind” mentality on the part of senior NMRC managers.
- If the NMRC wants to operate a QSL capable of working to WHO/ISO standards, then staff need training in what is expected of them. While extensive and ongoing training will be required, Phase 2 of this assignment will provide training in the key elements of operating a QSL facility in a GMP-compliant manner.

## CONCLUSIONS

This consultancy and assessment is the follow up to the original 2009 SPS report. Several substantive recommendations are made to enhance the effectiveness and efficiency of the NMRC, particularly in the registration of ARV/AM/ATB medications and to accelerate the processing of medicines on the Namibian EML.

This review reaffirms that the NMRC's current capacity is inadequate and offers recommendations for interventions to improve the situation. The NMRC would be better served by becoming a self-funding agency within the MoHSS, with fees based on a realistic financing model to fund all activities that Namibian law requires it to perform.

The most urgent tasks facing the NMRC Secretariat are:

- Becoming a self-funding agency within the MoHSS, and establishing proper registration and licensing fees to fund all NMRC functions, including the QSL.
- Until the NMRC becomes a self-funding agency within MoHSS, obtaining budget and headcount approval to hire sufficient scientific/technically capable staff to eliminate the registration dossier backlog, currently at over 700 dossiers.
- Allowing non-pharmacists to be trained to work as reviewers of medicines registration dossiers. This will require changes to job titles and job descriptions, and a renegotiation of pay scales within the Namibian government salary system.
- Rapidly implementing the web-based version of Pharmadex to enhance the NMRC's dossier review capabilities.
- Working with the CMS and other relevant government agencies to require that all medicines that the CMS tenders are previously registered with the NMRC.
- Determining whether the QSL provides value added to the NMRC and to the health and safety of the Namibian population and/or immediately close the QSL until such time as its added value is determined. If it is decided to operate the QSL, it should not be reopened until it has been certified as meeting WHO GMP or ISO 17025 standards.
- Changing the role of the QSL from randomly testing some medicines when they arrive in-country to testing all samples of medicines as part of the NMRC medicines registration process.
- Considering not relocating the QSL's location outside of Windhoek.
- Linking the Namibian Customs and Excise Department of the Ministry of Finance locations at Namibian ports of entry with the web-based version of Pharmadex such that it can, on a real time basis, ensure that imported medicines are registered with the NMRC. Restrict ports

of entry for medicines into Namibia to Hosea Kutako International Airport, and to a single border crossing from South Africa, both of which should be linked real-time with the Pharmadex database.

- Transferring responsibility for inspection and licensing of medicines stores in pharmacies, hospitals, clinics, warehouses, etc., to the PCN, together with the fees associated with this function.
- Adopting a capacity building model in its approach to operating an efficient and sustainable regulatory system. This approach will require that current deficiencies in structures, systems, and roles, which form the base of the model's pyramid, are addressed as the foundation of a sustainable institution. Countries need to periodically assess their regulatory capacity. In some instances, it has been recommended that such an assessment be carried out every five years.

## ANNEX A. LIST OF NMRC PERSONNEL MET AND INTERVIEWED

<b>Name</b>	<b>Title</b>
Mr. Johannes Gaeseb	Registrar of NMRC
Dr. Assegid Mengistu	TIPC Advisor
Mr. Pascal Rite	Head, Registration
Ms. Saren Kauhondamwa	Registration Pharmacist
Mr. Ruigi Njiriri	GMP Inspection & Licensing Pharmacist
Mr. Gilbert Habimana	Chief Pharmacist
Mr. Howard Masiyachengo	QSL Manager

## ANNEX B. STANDARD OPERATING PROCEDURE FOR QSL SAMPLING

### PHARMACEUTICAL CONTROL & INSPECTION QUALITY SURVEILLANCE LABORATORY

<b>TITLE:</b>	<b>SOP NO:</b> QSL 01-08	<b>PAGE:</b> 1 of 4
<b>Written by:</b> ..... <b>Date:</b> ..... Author	<b>Effective Date:</b> 1st August 2008	
<b>Reviewed by:</b> ..... <b>Date:</b> ..... Head of Section	<b>Revision Date:</b> 1st August 2009	
<b>Approved by:</b> ..... <b>Date:</b> ..... Registrar	<b>Revision No:</b> 1	<b>Document Level:</b> 2

#### 1.0 PURPOSE

To establish a procedure for sampling of pharmaceutical products from CMS.

#### 2.0 SCOPE

This applies to the sampling of pharmaceutical products from CMS.

#### 3.0 RESPONSIBILITY

This procedure is used by the following:

- (i) Staff from CMS
- (ii) Staff from QSL

#### 4.0 LOCATION

CMS (Receiving bay)

#### 5.0 DEFINITIONS

- (i) Sample – a portion of a material collected according to a defined sampling procedure.
- (ii) Batch -a quantity of any drug produced during a given cycle of manufacture
- (iii) Available sample – whatever total quantity of sample material is available.

(iv) Consignment – a quantity of a drug product supplied at one time in response to a particular request or order.

(v) Representative sample- sample obtained according to a sampling procedure designed to ensure that the different parts of a batch are proportionately represented.

## **6.0 REVISION**

6.1 Supersedes

Original document.

## **7.0 ATTACHMENTS/APPENDICES**

7.1 Sample Quantity Form SQF 001/08

7.2 Analytical Request Form ARF 001/08

## **8.0 PROCEDURE**

8.1 Sampling is done at the arrival of a new consignment at CMS.

8.2 The sampling process should be appropriately supervised by personnel from CMS. The sampling is done on a batch by batch process for batch release. The Sampling process is carried out at the receiving bay.

- Identify the consignment to be sampled. Take care to avoid the collapse of stacked containers during sampling. Check the product name, manufacturer and batch numbers. Verify the quantities with purchase orders.
- Complete sections A and B of the Analytical Request Form.
- Carry out visual inspection of the consignment for possible tampering, contamination, deterioration etc. Any visible defects should be counted categorized for all packages i.e. pellets, shippers, secondary and primary containers. Complete section C of the Analytical Request Form.
- Take samples from any part of the consignment in their original containers (random sampling). Individual packs should not be broken open for the purposes of sampling. Use the Sample Quantities Form as a guide on the number of samples required. The samples should be sufficient for:
  - (a) Initial Analysis
  - (b) Repeat analysis
  - (c) Retention

A single consignment of a product from a single manufacturer and labeled with a single batch number may be assumed to be uniform.

- The minimum size of the sample is determined by the requirement of the analytical procedure to be used to test the product.

- When a consignment is composed of two or three batches from the same manufacturer, a single sample will be taken from each batch provided that there is previous favorable documented experience with the product and manufacturer, and there is evidence from expiry date or other information that the batches were produced at approximately the same time.
- When a consignment consists of one very large batch and there is little experience with the product, two samples will be taken from different sampling units.
- When the quantity of the available sample is not adequate as required by the Sampling Quantities Form and there is need to adjust the quantity of the sample to be taken, the following steps should be taken.
  - (i) Advise the QSL Manager on the quantity of sample to be taken.
  - (ii) Take one or two containers as described in 7.6 above.
  - (iii) If there is need to open the container for sampling, the container to be sampled should be cleaned prior to sampling.
  - (iv) The container used to store the sample should not interact with the sampled material nor allow for contamination. It should also protect the sample from light, air and moisture as required by the storage directions of the product.
  - (v) The container used to store the sample should be properly labeled with appropriate details such as name of product, batch/lot number, quantity, date of manufacture and/or expiry and storage conditions (if necessary)The sample container should be identified as it no longer contains the quantity of product stated on the label.
  - (vi) The labels should be applied at the time of sampling.
- Take the samples to the dispatch bay for release procedures from CMS.
- The samples should immediately be taken to QSL for recording and storage.
- No samples shall be returned to CMS.

## **9.0 RECORDS**

During the course of implementing this procedure, appropriate records are generated and maintained for not less than five (5) years.

## **10.0 REFERENCE**

- 10.1 WHO Guideline for sampling of pharmaceuticals and related materials 2004
- 10.2 MR 4.00- Writing Standard Operating Procedure.

## **Sample Quantities for Submission to QSL**

The procedure describes the sample quantities to be submitted to QSL for analysis. Samples are required for: (1) Analysis (2) Re-analysis (3) Storage

### **A) Single/Fixed Dose Units**

Tablets, capsules, film coated tablets, powder and solutions for injection (ampoules), suppositories.

Sample Quantity	Number of Containers
Pack size	
100 or less	4
200	2
500 or more	1

For blister packaging: Package sizes are usually 20, 50 or 100 units.

Package size 20 units: 10 packs

Package size 50 units: 4 packs

Package size 100 units: 2 packs

The minimum quantity should be 200 tablets/capsules

### **B) Liquid and Ointments**

The package sizes usually ranges from 5ml/g (eye) up to 250 ml/g.

Sample Quantity	
Pack size	Number of units
5 ml/g to 50 ml/g	25
Others	10

The minimum quantity should be 200 ml/g

### **C) Solutions for Infusion**

The solutions for infusion are packed in bottles (glass or plastic) with fill volumes ranges from 500 ml to 21 (approximately)

Sample Quantity	Number of units
Pack size	
500 ml or more	2



ANNEX D. NMRC QUARTERLY REPORTS

Year: 2008 Sub-Division: **PC I**  
 Month: January Section: **Registration**

Planning Monitoring Report

4TH QUARTER 2012-13 - REGISTRATION SECTION

OBJECTIVE	ACTIVITIES	MONTHS			Expected Outcome	Outcome	Remarks
		J	F	M			
Work Performance Assessment of staff of the Sub-division	1. Evaluating response to non-compliance queries	x	0	x	Finalize the evaluation process before recommendation for their registration to PAC and Council	49 responses for non compliance responded to. All were passed	Karnataka Antibiotic, Gvs Pharma and Sandoz SA queries
	2. Dossiers received and entered into Pharmadex	x		x	Receive and enter into the data base all submissions as they are received	104 dossiers received and entered into the data base	The inflow of dossier receipts is overwhelming
	3. Compassionate clearance certificates processed	x	x	x	Process all applications for compassionate clearance certificates	95 compassionate clearance certificates processed	Routine
	4. Collection of state revenue under fees payable to the Registrar	x	x	x	Enhance revenue collection for state	NS 3,383,100.00 collected	Reasonable retention fees collected
	5. Post registration amendment queries	0	0	x	Process and respond	19 post-registration amendment queries were processed.	Mainly Veterinary medicines
	6. Evaluation of dossiers and compiling of reports for the evaluated dossiers	x	x	x	Eliminate backlog	55dossiers evaluated.	Fast tracking mode, no retreat
	7. Recommend to Council products to be registered	0	x	0	Number of products registered	Lot 27, comprising of 69 human medicines and Lot 7 containing 15 Veterinary Medicines were registered on 07/02/2013	Lot 28 with 59 human medicines recommended for registration
	8. Meetings of Pharmaceutical & Analytical Committee	0	x	x	Meetings conducted out of expected	2 meetings were held on 5th February 2013 and 27th March 2013	To deliberate and pass essential decisions for submission to council on 04/04/2013

Year: 2008 Sub-Division: **PCI**

**Planning Monitoring Report**

Month: January Section: **Registration**

4TH QUARTER 2012-13 - REGISTRATION SECTION			
9. Meetings of Council	0	x	0
			Meetings conducted out of expected
			One meeting was held on <b>07/02/2013</b>
			Routine

Year: ~~2008~~  
 Month: January  
 Sub-Division: PC I  
 Section: Registration

Planning Monitoring Report

1ST QUARTER 2013-14 - REGISTRATION SECTION

OBJECTIVE	ACTIVITIES	MONTHS			Expected Outcome	Outcome	Remarks
		A	M	J			
	1. Evaluating response to non-compliance queries	0	0	X	Finalize the evaluation process before recommendation for their registration to PAC and Council	1 response for non compliance responded to.	Rx-Cefuroxime from Cachet
	2. Dossiers received and entered into Pharmadex	X	X	X	Receive and enter into the data base all submissions as they are received	58 dossiers received and entered into the data base	Routine
	3. Compassionate clearance certificates processed	X	X	X	Process all applications for compassionate clearance certificates	115 compassionate clearance certificates processed	Routine
Work Performance Assessment of staff of the Sub-division	4. Narcotic permits processed	X	X	X	To process all Narcotic Licence Permit applications placed in the respective period;	permits processed	Routine
	Submission of reports in terms of the Convention on Psychotropic Substances of 1971	0	0	X	Report submitted	Comply with the statute on the International Narcotic Convention	Routinely submitted
	5. Collection of state revenue under fees payable to the Registrar	X	X	X	Enhance revenue collection for state	N\$ 1,329,075.00 collected	Reasonable retention fees collected
	6. Post registration amendment queries	X	X	X	Process and respond	51 post-registration amendment queries were processed.	
	7. Evaluation of dossiers and compiling of reports for the evaluated dossiers	X	X	X	Eliminate backlog	53 dossiers evaluated.	Fast tracking mode, no retreat
	8. Recommend to Council products to be registered	X	0	X	Number of products registered	Lot 28, and 29 comprising of 97 human medicines and 3 veterinary medicines were registered	Routine

Year: 2008  
 Month: January

Planning Monitoring Report

Sub-Division: PC I  
 Section: Registration

2ND QUARTER 2013-14 - REGISTRATION SECTION

OBJECTIVE	ACTIVITIES	MONTHS					Expected Outcome	Outcome	Remarks
		J	A	S					
Work Performance Assessment of staff of the Sub-division	1. Evaluating response to non-compliance queries	x	x				Finalize the evaluation process before recommendation for their registration to PAC and Council	38 response for non compliance medicines which were not captured in the NVMR	Mainly veterinary medicines which were not captured in the NVMR
	2. Dossiers received and entered into Pharmadex	x		x			Receive and enter into the data base all submissions as they are received	80 dossiers received and entered into the data base	Routine
	3. Compassionate clearance certificates processed	x		x			Process all applications for compassionate clearance certificates	97 compassionate clearance certificates processed	Routine
	4. Narcotic permits processed	x		x			To process all Narcotic Licence Permit applications placed in the respective period;	permits processed	Routine
	Submission of reports in terms of the Convention on Psychotropic Substances of 1971	0	0	x			Report submitted	Comply with the statute on the International Narcotic Convention	Routinely submitted
	5. Collection of state revenue under fees payable to the Registrar	x	x				Enhance revenue collection for state	N\$ 478,187.00 collected	Reasonable retention fees collected
	6. Post registration amendment queries	x	x				Process and respond	161 post-registration amendment queries were processed.	Change of names, re-issuing of certificates of registration
	7. Evaluation of dossiers and compiling of reports for the evaluated dossiers	x	x				Eliminate backlog	53 dossiers evaluated.	Fast tracking mode, no retreat
	8. Recommend to Council products to be registered	0	0	x			Number of products registered	Lot 30, comprising of 34 human medicines were registered	Routine

Year: 2008 2012

Planning Monitoring Report

Sub-Division: PC I

Month: January

Section: Registration

3RD QUARTER 2013-14 - REGISTRSTION SECTION

OBJECTIVE	ACTIVITIES	MONTHS			Expected Outcome	Outcome	Remarks
		O	N	D			
Work Performance Assessment of staff of the Sub-division	1. Evaluating response to non-compliance queries	x	x		Finalize the evaluation process before recommendation for their registration to PAC and Council	0 response for non compliance responded to.	Hectic regulatory activity left no room for evaluation whatever query that was responded to.
	2. Dossiers received and entered into Pharmadex	x			Receive and enter into the data base all submissions as they are received	44 dossiers received and entered into the data base	Routine
	3. Compassionate clearance certificates processed	x	x		Process all applications for compassionate clearance certificates	110 compassionate clearance certificates processed	Routine
	4. Narcotic permits processed	x			To process all Narcotic Licence Permit applications placed in the respective period;	permits processed	Routine
	Submission of reports in terms of the Convention on Psychotropic Substances of 1971	0	0	x	Report submitted	Comply with the statute on the International Narcotic Convection	Routinely submitted
	5. Collection of state revenue under fees payable to the Registrar	x	x		Enhance revenue collection for state	NS 844,730.00 collected	Reasonable retention fees collected
	6. Post registration amendment queries	x	x		Process and respond	18 post-registration amendment queries were processed.	There was simply no time to respond to queries
	7. Evaluation of dossiers and compiling of reports for the evaluated dossiers	x	x		Eliminate backlog	29dossiers evaluated.	Fast tracking mode, no retreat
	8. Recommend to Council products to be registered	0	0	x	Number of products registered	1 of 31, and 32 comprising of 73 human medicines and 12 vet medicines were registered	Routine

**INSPECTION AND LICENSING**

**QUARTER 3 REPORT**

**2013/14 FINANCIAL YEAR**

(1) Inspections

The following health facilities were inspected:

Pharmacies 17

Nurses' clinics 9

Veterinarian clinics 1

Medical Practitioners (Dispensing) 7

Hospital Pharmacies 3

Whosalers 2

Others (for example complimentary medicine practitioners) 2

41

(2) Applications for renewal of licences received during this quarter (dispensing licences for medical practitioners, section 31(1) licences, complementary medicine licences, veterinarians, import licences), were processed.

(3) One meeting of the Legal and Advertising Committee was held on 06/11/2013. This requires preparations, mainly action on minutes of the previous meeting, compiling the minutes of the meeting and taking action on decisions taken at the meeting.

(4) The inspector was involved in auditing the ordering and receiving of medicines by health facilities. This activity was limited to Health Centres and clinics.

(5) Receiving and documenting applications for licences (new ones and for renewal) and putting them on the agenda for the Legal and Advertising Committee meeting.

(6) Took part in scheduled and ad hoc meetings and attended to correspondence during the quarter

(7) Attended training on registration of medicines 17-18 October 2013

(3) Number of manufacturing establishments registered

None

41  
31  
36  
50  
-----  
158

## Quarter 1 2013/14 Narrative report

### 1. INSPECTION AND LICENSING

#### ACHIEVEMENTS

Some time was spent inspecting facilities that were the subject of applications for section 31(1), 31(3) and 31(5)(c) licences to facilitate completion of evaluation/consideration of applications for these licences.

The following number of facilities was inspected over the reporting period

<b>Month</b>	<b>No of facilities</b>
January	6
February	6
March	19
<b>Total</b>	<b>31</b>

31

#### CHALLENGES

- ✓ There is only one medicines Inspector for the whole country. As a consequence, inspections required to be carried out for applications and queries cannot be done on time.
- ✓ The planned inspections of manufactures outside of the country have not taken place due to lack of financial resources.
- ✓ The use of local inspectors to fill that gap created by shortage of staff has not materialized yet.

**INSPECTION AND LICENSING**

**QUARTER 2 REPORT**

**2013/14 FINANCIAL YEAR**

(1) Inspections

The following health facilities were inspected:

Pharmacies 7

Nurses' clinic 5

Others (for example complimentary medicine practitioners 3

(2) All applications for licences organized by category (dispensing licences for medical practitioners, section 31(1) licences, complementary medicine licences, veterinarians), filed according to newly established data bases for easy follow-up and tracing. Licensing matters has become a major activity.

(3) One meeting of the Legal and Advertising Committee was held on 07/08/2013. This requires preparations, mainly action on minutes of the previous meeting, compiling the minutes of the meeting and taking action on decisions taken at the meeting.

(4) Sorted out dispensing licences for veterinarians and follow up on those who have not paid for the licences. 28 licences have now been issued out of 58 approved applications.

(5) Receiving and documenting applications for licences (for renewal and new ones) and putting them on the agenda for the Legal and Advertising Committee. The following applications were received:

Medical practitioners 2

Nurses 13

Importer 5

36

(6) Took part in meetings and attended to correspondence during the quarter

**PC & I**

**Inspection and Licensing**

Quarter 1 Report

**Achievements**

- 1) Wrote and completed reports on inspections carried out in March 2013.
- 2) Inspected six (6) health facilities in Windhoek, Rehoboth and Okahandja.
- 3) Met and talked to Namibia Competasion commission on the involvement of Cipla Medpro SA and Cipla India in the Namibian pharmaceutical trade
- 4) Two guidelines were operationalised (1) Labelling of Dietary supplements and (2) Advertising and promotion of medicines
- 5) Inspected nine (9) private health facilities in Kavango, Kunene and Northern Regions.
- 6) Inspected and wrote of expired narcotics in fourteen (14) Public hospitals and two (2) Muilt Regional Medical Depot in Kavango, Kunene and the four (4) Northern Regions.
- 7) Preparation for the LAC committee meeting. Any action from the previous meeting was to be done by me
- 8) Attended the LAC meeting and wrote minutes for the meeting
- 9) Drafted and finalized reports for the nine (9) private health facilities inspected in Kavango, Kunene and Northern Regions.
- 10) Inspected one wholesaler Esindano pharmaceuticals for import licensing purposes
- 11) Created data base for applications for dispensing licences for veterinarians and sent out notices for them to pay for the licences.
- 12) Attended PC&I planning meeting at the NHTC
- 13) Carried out inspections of twelve (12) suppliers of various items including medicines to CMS to assess their contribution to the Namibian economy through creation of employment opportunities particularly for the previously disadvantaged citizens.

**Challenges**

- 1) Inadequate human resources. Only one inspector for the entire country
- 2) Inadequate budget to carry out the activities
- 3) The Legal and Advertising committee is very active and as its secretary to the committee it takes a lot of the inspector's time as the main player. A new secretary should be appointed.

**Way forward**

- Increase human resources

LAC - LEGAL + ADVERTISING COMMITTEE

NHTC - NAMIBIAN HEALTH TRANSFER CENTRE

## QUALITY SURVEILLANCE LABORATORY

### 3<sup>rd</sup> QUARTERLY REPORT

1<sup>st</sup> October – 31<sup>th</sup> December 2013

#### Achievements

QSL received 31 samples during the above period and analysed 36 samples (70.59%) in the same period from a total of 51 samples (20 samples backlog from previous quarter). Two samples (5.56%) failed analysis.

QSL started the review of the Quality Management Documents, Quality Policy Manual, Management System Procedures Manual and SOPs to incorporate the recommendations of the WHO consultant.

QSL received a Fourier transform infrared (FT-IR) equipment from the Global Fund. The equipment would be used to identify active pharmaceutical ingredients in medicines using the BP and USP libraries in the equipment.

The review of the SOPs is continuing to align them with the WHO prequalification requirements.

QSL staff attended training programmes in ISO/IEC 17025 requirements and internal auditing in Swakopmund and Laboratory Management , Safety and Good Laboratory Practice in Pretoria South Africa. The first training enabled QSL staff to be certified internal auditors of the laboratory management system while the second training equipped staff to implement GLP in the laboratory.

#### Constraints/Comments

The new friability and hardness tester equipments that were delivered in the second quarter and installed cannot be used because the friability tester has some nuts missing and the hardness tester is not compatible with the printer installed. The new FT-IR delivered in december does not contain BP and USP libraries and cannot be used. It is the responsibility of the equipment provider to ensure all issues are attended to.

QSL has not been able to recruit to increase staff complement to fully address the requirements proposed by the WHO consultant.

QSL was affected by the ban on payment to foreign organizations by cheques and the contract for Shimadzu HPLC was not paid in time and the equipment was not serviced. Arrangements are now being made for electronic transfer of funds.

1

36  
24  
61  
45  
-----  
106

## **QUALITY SURVEILLANCE LABORATORY**

### **4<sup>th</sup> QUARTERLY REPORT**

**1<sup>st</sup> January – 31<sup>st</sup> March 2013**

#### **Achievements**

QSL received 49 samples during the above period and analysed 24 samples in the same period. Two samples failed analysis. The number of samples analysed was low due to the stock take done in January, one analyst was on annual leave and three analysts participated in the annual stock take at CMS in March. The laboratory is recommended to liaise with CMS to reduce the number QSL staff needed for CMS stock take.

WHO agreed to provide a consultant to assist QSL achieve WHO Prequalification. QSL staff still show inadequate understanding on how to generate good quality raw data for analysis. The head of QSL is recommended to carry out in-house training on how to generate good quality raw data.

SOPs for new equipment were not finalized because there was no time. The laboratory is recommended to create time to develop and finalise SOPs for new equipment.

The new FT-IR has not yet been received and the advertisements for the hardness and friability testers have not been placed in the print media. The laboratory is recommended to follow up with GF on the placing of adverts for the tender for hardness and friability testers.

The adherence to SOPs was monitored and there were no transgressors. The use of SOPs in all activities should continue to be encouraged.

All three major equipments, two HPLCs and one UV-Vis spectrophotometer had maintenance and service contracts. The laboratory is recommended to make follow up on the renewal of contracts. The lab should contact the agent for Agilent HPLC in South Africa to draw up a new contract as the guarantee period is expiring in July 2013.

The laboratory has no checklist for the management of infrastructure. The laboratory is recommended to follow up with the sub-division.

Pharmaceutical and chemical waste were disposed according to waste disposal guidelines. The laboratory has limited containers for stocking chemical waste before disposal is done. The laboratory is recommended to procure bulk containers for storage of chemical waste before disposal.

## **QUALITY SURVEILLANCE LABORATORY**

### **1<sup>st</sup> QUARTERLY REPORT**

**1<sup>st</sup> April - 31<sup>st</sup> June 2013**

#### **Achievements**

QSL received 64 samples during the above period and analysed 61 samples in the same period.

QSL reviewed the Laboratory Information File (LIF) for WHO prequalification. The LIF was submitted to WHO electronically as requested. The other quality management documents are still undergoing review process.

The laboratory completed the SOP for operation and calibration of the new specord ultraviolet visible spectrophotometers and Agilent HPLC.

The laboratory completed the analysis of chloroquine sulphate oral solution 50mg/5mL for WHO proficiency testing. The results were submitted to WHO electronically as recommended.

The laboratory repaired 20L Labotec waterbath, 50L Labcon waterbath and Labotec laboratory hotplate.

QSL analyst provided lecturing services to NHTC.

#### **Constraints / Challenges**

There was limited time for the review of quality management documentation which due for review in August 2013.

#### **Recommendations**

The laboratory should allocate more time for the review of quality management documentation.

Preventative maintenance service contracts should be drawn up for new equipment as the guarantee period is expiring mid year.

The laboratory should propose a new service plan with the agent for the Beckman ultraviolet visible spectrophotometer.

## **QUALITY SURVEILLANCE LABORATORY**

### **2<sup>nd</sup> QUARTERLY REPORT**

**1<sup>st</sup> July – 30<sup>th</sup> September 2013**

#### **Achievements**

QSL received 6 samples during the above period and analysed 45 samples in the same period. All samples passed analysis.

QSL finalized the review of the Quality Management Documents - Laboratory Information File (LIF), Quality Policy Manual, Management System Procedures Manual.

QSL hosted a consultant from WHO whose objective was to advise the laboratory how to operate according to the principles of WHO guidelines for national pharmaceutical control laboratories. The consultant report has since been received from WHO.

QSL received two equipments from Global Fund, a hardness tester and a friability tester. The equipment will be installed soon by the agent.

QSL has started to implement the recommendations of the WHO consultant with the new laboratory plans having been sent to the consultant for review.

The review of the SOP's were started for those SOP's the consultant said inadequate and needed to be review. The review has been done on the procedure for purchasing and disposal of waste.

Two employees were funded by development partners were successfully absorbed by the ministry of health and social services.

The laboratory completed the calibrations of equipments.

QSL is in the process of making a contract for preventative maintenance for Agilent HPLC with Anatech who are the agents.

#### **Constraints**

The contracts for equipments have not yet been paid due to late release of funds.

The new contract for Agilent HPLC has not yet been finalised due to late response by the other party.

*TIPC 1<sup>st</sup> Quarter Report 2013/14*

**Main output /Achievements Oct 2013- Dec 2013**

**Pharmacovigilance**

**Passive surveillance**

A total of 26 spontaneous adverse event reports received during the 3rd quarter. All AMR reports – received through the spontaneous reporting system – were reviewed and entered in to the TIPC database. A backlog of 240 reports from 2012 and all the reports received in 2013 were entered in to the vigilow. A total of xx reports committed to the WHO data base.

**Active surveillance system**

**Implementation of the Active surveillance system**

The follow up of patients in the cohort stopped from from end of November 2013. cohort follow up form are being collected. A data quality check is done before pulling out the form from the patient care booklet. A total of 215 forms (83 from KIH and 132 from WCH) have been checked for missing data and collected after completing the missing infor from the PCB. The remaining will be collected in the 1<sup>st</sup> wk of Jan 2014.

Regulatory Pharmacovigilance

TIPC received 47 periodic Safety Update Report (PSUR) and 26 worldwide serious safety literature reports for from HCR.

**Therapeutics Information**

The TIPC responds to 4 therapeutics enquiry.

Volume 3 Issue 4 Medicines Watch is ready for printing. Printing company has been selected by Economizing Committee. Medicines Watch will be printed in January 2014. Collection of articles for the next issue started.

**Other Activities of the TIPC**

Participated on the 6th African Pharmacovigilance Consultants Network (Pharmacovigilance Sans Frontiers – PVSF) meeting in Accra, Ghana from 25th November to 29th November 2013.. Collected C/S test result of urine isolate

*TIPC 1<sup>st</sup> Quarter Report 2013/14*

**Constraints/Challenges**

The staff shortage issue remains unresolved. The TIPC computer is old and very slow making the data processing difficult.

**Recommendations/Way Forward**

Replace the TIPC computers with new computers.

Solicit support from MSH until new staff recruited.

## ANNEX E. NMRC JOB DESCRIPTIONS

### Job Description – Medicines Inspector

Supervisor: Chief Pharmacist: Pharmaceutical Control and Inspection  
Duty Station: Head Office, MoHSS, Windhoek  
Purpose of Job: Medicines Inspection

Main tasks and responsibilities:

#### 1. Medicines Inspection

- Part of the Secretariat of the Namibia Medicines Regulatory Council
- Carry out inspections, as scheduled, of all health facilities where medicines are kept
- Participate in inspection of all health facilities for licensing purposes
- Carry out inspection at non-pharmaceutical wholesalers that keep schedule 0 medicines and pharmaceutical wholesalers
- Inspect all points of entry as well as open markets
- Inspect pharmaceutical manufacturers both locally and internationally
- Write report following each inspection

#### 2. Planning and budgeting

- Carry out annual planning and budgeting necessary for activities related to medicines inspection, in co-ordination with supervisor
- Ensure that planned activities are carried out within budget limits

#### 3. Report writing

- Write contribution re medicines inspection for Divisional annual report

#### 4. Training

- To initiate and maintain a schedule for training of Regional Pharmacists as Medicines Inspectors
- To initiate training for Custom officers and Police officers on medicines control

#### 5. Miscellaneous

- Carry out other official duties assigned by the supervisor

## **TIPC ADVISER**

The Therapeutics Information and Pharmacovigilance Centre (TIPC) adviser is responsible for providing day-to-day technical direction to the TIPC in Namibia. S/he is a liaison between technical partners, particularly the Strengthening Pharmaceutical Systems (SPS) project implemented by Management Sciences for Health and the TIPC of the Ministry of Health and Social Services (MoHSS). The TIPC adviser provides training, strategic technical guidance, ensures implementation of TIPC planned activities, and works closely with the TIPC coordinator to ensure the fulfillment of the objectives of the TIPC.

### Key Areas of Focus

- Liaise with the SPS project to develop and translate technical inputs from SPS into the implementation of activities of the TIPC.
- Under the guidance of the TIPC Working Group, and working collaboratively with the TIPC coordinator, develop TIPC technical strategies and work plans.
- Establish and maintain regular communication with the Directorate of Special Programmes (DSP) and the public health programmes including HIV/AIDS, TB and Malaria so as to ensure that pharmacovigilance activities are included in programme plans.
- Prepare and submit to the Technical Advisory Committee (TAC) summary reports of identified medicines safety issues for benefit/risk assessment.
- Develop and maintain communication with all relevant stakeholders on the implementation of the mandate of the TIPC.
- Serve as a member of the TIPC expert committee to review ADR reports, generate hypotheses, establish causality, and make proposals to inform regulatory and treatment guidelines decisions.
- Responsible, in collaboration with the TIPC coordinator, for developing training materials and conducting all trainings related to therapeutics information and pharmacovigilance activities in Namibia.
- Mentor the TIPC coordinator, Medical Control Centre (MCC) staff and key members of guidelines committees on key technical areas including causality assessment and pharmacoepidemiology.
- Support TIPC in the development and implementation of systems for reporting of adverse drug reactions and strengthen systems to improve pharmacovigilance in Namibia.

- Provide adverse drug reaction summary reports to MCC (through Division: Pharmaceutical Services), Directorate of Special Programs, HIV/AIDS Technical Advisory Committee, and Therapeutics Committees.
- Provide timely routine reports to MoHSS and development partners on the functioning of the TIPC.

Minimum requirements

- Health care professional preferably medical doctor or pharmacist with postgraduate degree in any of the following areas: clinical pharmacology, epidemiology, clinical pharmacy, public health, or pharmacoepidemiology.
- A minimum of 3 years hands-on experience working in a national pharmacovigilance center and/or a medicine information center is required.
- Work experience with adverse events reporting systems including passive and active surveillance methods required.
- Proficiency in ICH E2B, Individual Case Safety Reports, VigiFlow®, WHOART, MedRA, and other pharmacovigilance tools is an advantage.
- Proficiency in English, including speaking, understanding and writing.
- Demonstrated computer skills in Microsoft Office Suite applications, including Word, Excel, PowerPoint, and Publisher.

Competency requirements

- Demonstrated managerial, organization skills
- Ability to write reports and analyze and interpret data
- Have strong interpersonal skills and ability to work with people of different backgrounds
- Apply sound problem solving skills to ongoing challenges

Job title:	TIPC Senior Pharmacist	TIPC Pharmacist
Duty location:	TIPC	TIPC
Reports to:	Chief Pharmacist, PC & I	TIPC Coordinator
Job summary:	<ul style="list-style-type: none"> <li>• Provides direct technical &amp; administrative services for the functioning of the TIPC</li> <li>• Ensures implementation of TIPC planned activities and works closely with the TIPC staff and other stakeholders to ensure fulfillment of TIPC's objectives</li> </ul>	Provides day-to-day operational services on medicine information and pharmacovigilance to clients and stakeholders
Main duties and responsibilities:	<ul style="list-style-type: none"> <li>• Implement systems and strategies for improving ADR reporting</li> <li>• Implement systems and strategies for collecting, acknowledging, analysis, documentation, feedback, and reporting of ADR reports</li> <li>• Design/review pharmacovigilance tools and guidelines</li> <li>• Develop/review internal SoPs</li> <li>• Provide technical assistance to TIPC personnel in the management of medicine safety risks</li> <li>• Contribute to the improvement and maintenance of the TIPC website</li> <li>• Compile reports and summary statistics on TIPC activities for reporting</li> <li>• Contribute to the publication of the TIPC bulletin</li> <li>• Contribute to development of TIPC's training and advocacy materials</li> <li>• Contribute to the organization and delivery of TIPC trainings and advocacy activities</li> <li>• Coordinate the activities of TIPC staff</li> <li>• Responsible for the accountability, security, safety, maintenance, and cleanliness of the TIPC facilities/equipment</li> </ul>	<ul style="list-style-type: none"> <li>• Receive, acknowledge, process, and respond to and document therapeutics queries</li> <li>• Receive, acknowledge, review, verify, analyze, and document ADR reports</li> <li>• Contribute articles to the TIPC bulletin</li> <li>• Conduct TIPC outreach activities</li> <li>• Promote TIPC through advocacy, information, and educational activities</li> <li>• Participate and contribute in clinical ward rounds at WCH and KIH</li> <li>• Conduct TIPC-related training activities</li> <li>• Provide support to therapeutics committees, TAC, EMLC, STG, medicine safety review and other committees</li> <li>• Provide support to INRUD</li> <li>• Participate in medicines and therapeutics-related research</li> <li>• Orient new staff, visitors, students, and interns</li> </ul>
Minimum qualifications:	Pharmacist, preferably with postgraduate degree in any of the following areas: clinical pharmacology, epidemiology, clinical pharmacy, public health, or pharmacoepidemiology.	Pharmacist

Experience:	A minimum of 3 years hands-on experience working in a national pharmacovigilance center and/or a medicine information center	
Skills:	<p>Proficiency in:</p> <ul style="list-style-type: none"> <li>• ICH E2B, Individual Case Safety Reports, VigiFlow®, WHOART, MedRA, and other pharmacovigilance tools</li> <li>• Proficiency in English, including speaking, understanding and writing.</li> <li>• Demonstrated computer skills in Microsoft Office Suite applications, including Word, Excel, PowerPoint, and Publisher.</li> </ul> <p>Demonstrated managerial, organization skills. Ability to write reports, analyze, and interpret data.</p>	<ul style="list-style-type: none"> <li>• Ability to write reports, analyze and interpret data.</li> <li>• Strong interpersonal skills and ability to work with people of different backgrounds.</li> <li>• Apply sound problem solving skills to ongoing challenges.</li> <li>• Strong organizing, planning, and prioritizing skills.</li> <li>• Capacity to operate both as a team player in large diverse teams as well as individually.</li> <li>• Self-motivated and maintain sound levels of work ethic.</li> </ul>

## **JOB DESCRIPTION – Principle Pharmacist, Medicines Registration**

Supervisor: Chief Pharmacist: PC & I  
Duty Station: Head Office, MoHSS, Windhoek  
Purpose of Job: Medicines Registration

Main tasks and responsibilities:

1. Registration of medicines
  - Part of Secretariat of the Namibia Medicines Regulatory Council
  - Scrutinize all submissions for registration to determine completeness of dossiers
  - Review dossiers for registration
  - Ensure safekeeping of medicine dossiers
  - Liaise with parties applying for registration
  - Process registration and issue certificates for items approved for registration
  - Ensure Medicines Register is kept up to date.
  - Supervise staff in the Medicines Registration Section
2. Planning and Budgeting
  - Carry out annual planning and budgeting necessary for activities related to medicines registration, in co-ordination with supervisor
  - Ensure that planned activities are carried out within budget limits
3. Report writing
  - Write contribution of medicines registration for Divisional\_ annual report
4. Supervision and Training
  - Supervise staff in the Medicines Registration Section
  - Determine training needs and develop/conduct training programmes
5. Miscellaneous
  - Carry out other official duties assigned by the supervisor

**MINISTRY OF HEALTH AND SOCIAL SERVICES**  
Directorate: Tertiary Health Care and Clinical Support Services  
Division: PHARMACEUTICAL SERVICES

**JOB DESCRIPTION:**  
**CHIEF PHARMACIST: PHARMACEUTICAL CONTROL AND INSPECTION**  
**(REGISTRAR OF MEDICINES)**

**Objectives:**

1. To plan, coordinate and control the effective functioning of the medicine registration and import control systems and the pharmaceutical inspections in terms of applicable legislation.
2. To provide secretarial services to the Namibia Medicines Regulatory Council (NMRC).

**Functions:**

1. Manage the NMRC Secretariat.
2. Ensure the compliance with legal and statutory requirements on medicines control.
3. Draw up and implement the work plans for the subdivision in consultation with the Council.
4. Draw up annual reports for the subdivision and on Council activities.
5. Assist the Council and the Minister in ensuring that medicines control legislation is up to date.
6. Bring any vacancies in the Council and committees to the attention of the Minister and the Council, respectively.
7. Manage training of staff in the subdivision and other cooperating partners.
8. Coordinate and supervise the activities of the inspectorate.
9. Perform other functions as assigned or directed by the superiors.

**MINISTRY OF HEALTH AND SOCIAL SERVICES**

**DIRECTORATE TERTIARY HEALTHCARE AND CLINICAL SUPPORT SERVICES**

**DIVISION PHARMACEUTICAL SERVICES**

**SUB DIVISION PHARMACEUTICAL CONTROL AND INSPECTION**

**REGISTRATION SECTION**

Post designation	:	Senior Pharmacist grade 6
1 post	:	Windhoek
Salary	:	N\$ 248 234 – N\$ 296 663
Fixed Overtime	:	N\$ 132 819 per annum

Minimum requirements: B-Science degree in Pharmacy plus registration with the Pharmacy Council of Namibia or authorization by Ministry to practice as a pharmacist in Namibia. The candidate must have at least 5 years of experience in the related field of activity.

The good candidate is expected to have the following basic requirements;

- Regulatory experience relating to the assessment of registration application dossiers
- To be conversant with regulatory issues relevant to the interpretation of the Medicines and Related Substances Control Act, Act 13 of 2003
- To have basic knowledge / experience on the art of manufacture of pharmaceuticals

The duties of the incumbent will be;

- Evaluate applications for registration of medicines submitted to the Secretariat of the Namibia Medicines Regulatory Council
- Prepare reports on the evaluated data for the relevant committees of the Council
- Manage the communications with applicants on the findings and equally evaluate responses to queries received from the applicants
- Finalize the registration process after approval by Council, maintain the registration data base etc.

Enquiries; Mr. Johannes Gaeseb; Registrar of Medicines

Post designation	Pharmacist grade 7
2 posts	Windhoek
Salary	N\$ 203 638 – N\$ 243 367
Fixed overtime	N\$ 108 957 per annum

**Minimum requirements:** B-Science degree in Pharmacy; registration with the Pharmacy Council of Namibia or authorization by Ministry to practice the pharmacy profession in Namibia. The candidate must have at least two years of experience in the related field of activity

The right candidate will be that person who is energetic, must have the drive to learn very fast new activities related to regulatory activities and is self-driven

The duties will be similar to those of the Senior Pharmacist but scaled down depending on the level of judgment required.

Enquiries; Mr. Johannes Gaeseb; Registrar of Medicines

# ANNEX F: US AND UK GMP INSPECTOR JOB DESCRIPTIONS

The screenshot shows the FDA website's 'About FDA' section, specifically the 'Consumer Safety Officer Positions at FDA' page. The page is titled 'Consumer Safety Officer Positions at FDA' and includes a sub-header 'FDA Hiring Initiative'. The main content area is divided into several sections: 'Description of Position', 'Grade (Salary) Levels', 'Qualifications', and 'Geographic location'. A sidebar on the left lists various job categories under 'Working at FDA', with 'Consumer Safety Officer Positions at FDA' highlighted. The footer contains contact information for the FDA, social media icons, and a list of links for different departments and services.

U.S. Department of Health & Human Services

**FDA** U.S. Food and Drug Administration  
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## About FDA

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### Working at FDA

- Career Descriptions
- Attorney Positions at FDA
- Biologist Positions at FDA
- Chemist Positions at FDA
- Consumer Safety Officer Positions at FDA**
- Engineer Positions at FDA
- Information Technology Positions in FDA
- Medical Officer Positions at FDA
- Microbiologist Positions at FDA
- Pharmacist Positions at FDA
- Pharmacologist Positions at FDA
- Statistician Positions at FDA

### Consumer Safety Officer Positions at FDA

#### FDA Hiring Initiative

The Food and Drug Administration is recruiting for 1,300 medical and science positions to fill critical needs. More about the FDA hiring initiative

#### Description of Position

FDA consumer safety officers perform duties that may include:

- investigating complaints of injury, illness, or death caused by an FDA-regulated product
- initiating actions against violators
- advising industry, state and local officials and consumers on enforcement policies, methods, and interpretation of regulations
- planning and directing regulatory programs
- developing inspection procedures and techniques
- coordinating the review process of New Drug Applications (NDAs)

#### Grade (Salary) Levels

The federal General Schedule (GS) grade levels at which consumer safety officer positions are most commonly filled are:

- GS-5 through 13 at the headquarters level
- GS-5 through 11 at the field level

(Note: Higher grade levels in both headquarters and field offices are available based on either peer review of individual accomplishments or supervisory responsibilities.)

For a list of GS-grade salaries, see the Office of Personnel Management Web site.

#### Qualifications

Basic qualifications required for all grades in this position include:

- a full course of study at an accredited college or university leading to a bachelor's or higher degree, including 30 semester hours in one or a combination of biological sciences, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, or related scientific fields that provide knowledge directly related to consumer safety officer work
- or 30 semester hours of course work as described above plus appropriate experience or additional education. The required 30 semester hours can include up to 8 semester hours in statistics or course work that includes the principles, theory, or practical application of computers or computer programming.

To qualify for higher-graded positions, candidates must have additional amounts of either specialized experience or directly related education. The amount of additional experience or education required depends on the grade of the position.

#### Geographic location

FDA consumer safety officers are located in headquarters (suburban Washington, D.C.) and in FDA facilities throughout the country.

Page Last Updated: 07/17/2009  
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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**FDA** U.S. Food and Drug Administration  
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Silver Spring, MD 20993  
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U.S. Department of Health & Human Services

U.S. Department of Health & Human Services
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## U.S. Food and Drug Administration

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- Medical Officer Positions at FDA
- Microbiologist Positions at FDA
- ▶ Pharmacist Positions at FDA
- Pharmacologist Positions at FDA
- Statistician Positions at FDA

### Pharmacist Positions at FDA

#### FDA Hiring Initiative

The Food and Drug Administration is recruiting for 1,300 medical and science positions to fill critical needs. More about the FDA hiring initiative

#### Description of Position

Pharmacists at FDA perform duties that include:

- Compounding of prescriptions for physicians, dentist and other licensed practitioners
- Formulation, preparation, bulk compounding, selection, dispensing and preservation of drugs, medicines and chemicals
- Research and investigation in developing original techniques of compounding and making available for use new investigational drugs
- Advising on drug therapy and usage
- Some positions involve the evaluation of drug proposals submitted by private industry and the surveillance of marketed drugs for safety and efficacy
- Responsible for the proper interpretation of prescriptions and the dispensing of products as prescribed
- Advising on significant new drugs and developments in the pharmaceutical, chemical and medical fields

#### Grade (Salary) Levels

The federal General Schedule (GS) grade levels at which these positions are most commonly filled are GS-9 through 13 at the headquarters level. For a list of GS-grade salaries, see the Office of Personnel Management Web site.

#### Qualifications

For GS-9	Successful completion of a 5-year course of study leading to a bachelor's or higher degree in pharmacy from an approved pharmacy school, or 1 year of professional pharmacy experience equivalent to at least GS-7.
For GS-11	Successful completion of a 6-year course of study leading to a Doctor of Pharmacy (Pharm.D) degree; 1 year of professional pharmacy experience equivalent to at least GS-9; or, for research positions, completion of all of the requirements for a master's or equivalent degree in a related scientific field.
For GS-12/13	Specialized experience is required equivalent to the next lower grade level.

#### Geographic Locations

Pharmacists are located only in headquarters (suburban Washington, D.C.).

Page Last Updated: 07/17/2009

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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#### U.S. Food and Drug Administration

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- Consumers
- Industry
- Health Professionals
- FDA Archive

U.S. Department of Health & Human Services

Safeguarding public health



**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**

**Position:** GMP Inspector  
**Location:** National  
**Division:** Inspection, Enforcement and Standards  
**REF NO:** IE129

**Salary Pay Band: £45,299 - £61,976**  
**Circa: £48,000 (dependant on location)**

**Progression to the maximum of the salary range will be dependent on performance**

The Medicines and Healthcare products Regulatory Agency (MHRA), an Executive Agency of the Department of Health, is responsible for safeguarding public health by ensuring that all medicines, healthcare products and medical equipment meet the appropriate standards of safety, quality, performance and efficacy.

**Purpose of Role:**

GMP Inspectors work as part of the GMP Inspection team to reduce risk and improve the quality of medicinal products for patients, by performing inspections at a wide range of sites in the UK and overseas, to assess the compliance of organisations with their legal obligations.

**Key responsibilities:**

- To organise and conduct inspections at manufacturing, importers, wholesale dealers and hospital sites to ensure medicinal products are manufactured in compliance with EU GMP and national marketing authorisations.
- For UK sites, GMP Inspectors review compliance reports and use inspection outputs to identify a risk rating for sites in accordance with the Agency's Risk Based Inspection programme.
- To work with other Regulatory Agencies and participate in EMA inspections in accordance with the Compilation of Community procedures.

Medicines and Healthcare products Regulatory Agency

The MHRA logo is a black oval with the letters 'MHRA' in white, bold, sans-serif font.

- To support the continued development of the GMP/GDP Inspectorate quality system by maintaining current knowledge and expertise in relevant scientific, professional and administrative matters.
- To undertake extensive travel within the UK and conduct numerous overseas inspection tours, totalling approximately 8 weeks per annum.
- Provide advice to stakeholders including participation in MHRA symposia and external meetings.
- Participate in joint/shadow inspections to expand knowledge base of inspectors e.g. GDP or other GXP inspections and WHO and EDQM inspections.

**Essential criteria to apply: (shortlist and interview criteria)**

1. Degree in a relevant science, medical or engineering degree (e.g. pharmacy, chemistry, microbiology, pharmacology, biochemistry, biology, medicine, engineering)
2. Extensive experience working in a Good Manufacturing Practice environment, which should include time in pharmaceutical manufacturing and/or quality assurance
3. Excellent communication verbal, written and interpersonal skills
4. Proven ability to write and review technical documents
5. Good planning and organisational skills to meet tight deadlines and manage multiple priorities
6. Proven ability to work unsupervised for long periods of time, but also able to work collaboratively within a close team environment
7. Proven ability to analyse and identify issue and take appropriate actions
8. Proven ability to make sound decisions and influence key stakeholders
9. Proven ability to take responsibility for results

The above criteria will be used when shortlisting applications for interview and as a basis for the interview questions. ***It is therefore important that you clearly explain on your application form how you meet the essential criteria.***



We are an equal opportunities employer and welcome applications from suitably qualified people regardless of, gender, sexual orientation, marital status, race, religion, politics or disability.

**Additional Information**

Please note that all positions in the MHRA require good all round I.T. skills, particularly MS Office. However, some positions require more specialist skills. Please refer to the essential criteria for the post above for more detailed information about the I.T. requirements of this post.

Please note that the full salary pay range for these roles is £45,299 - £61,976, Progression to the maximum of the salary range will be dependent on performance.

If these challenges inspire you, you can download further information and apply on-line via our website at [www.mhra.gov.uk](http://www.mhra.gov.uk). Similarly you can download our application at this address and send your completed form via email to [jobs@mhra.gsi.gov.uk](mailto:jobs@mhra.gsi.gov.uk).

**The closing date for applications is 20/7/2011.**



## ANNEX G. PHOTOS TAKEN OF NMRC AND QSL

Licensing Section:

Registration Dossiers yet to be reviewed (approx. 700)



Licensing Section:  
Registration Dossiers yet to be reviewed (approx. 700)



Registration dossiers overflowing into corridors



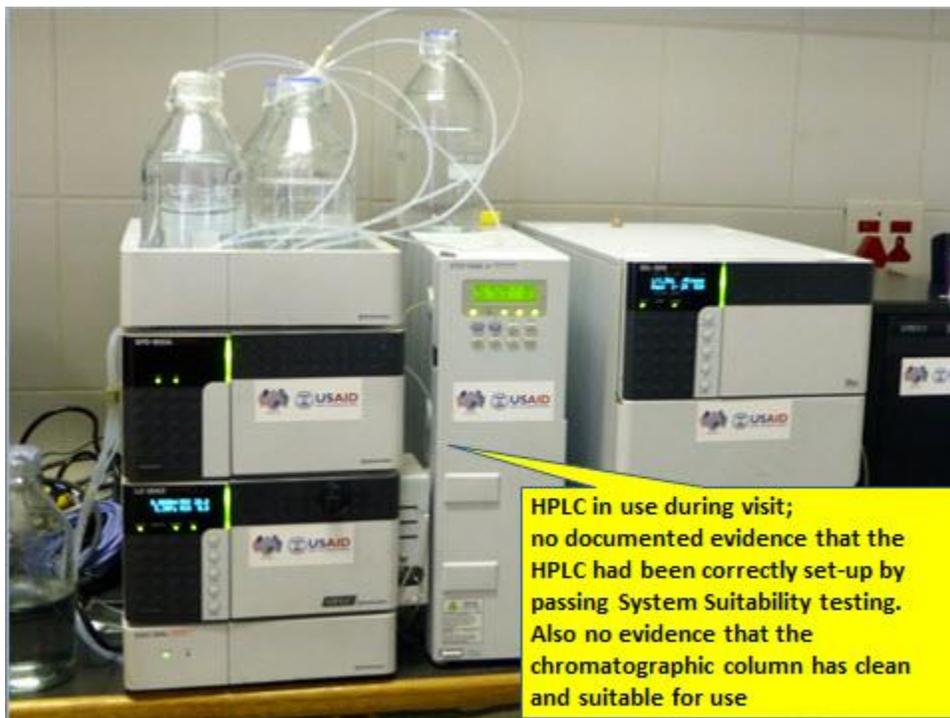
**Quality Surveillance Laboratory**

SOP-EQUIP 010/02 15 February 2010

Date	Feed water pressure In/out (bar)	RO Feed water conductivity (uS)	RO permeate conductivity (uS)	Product Resistivity (MΩcm)	RO rejection (%)	Temp °C	Signature, Date
20/06/12	4,2	681	48,3	8,7	90,3	21,4°C	[Signature]
18/07/12	5,3	702	40,4	9,2	91,1	24,2°C	[Signature]
23/08/12	6,2	651	42,2	8,1	91,2	21,3°C	[Signature]
16/09/12	4,1	781	38,1	9,1	94,1	26,1°C	[Signature]
12/10/12	5,1	701	50,2	8,2	93,2	24,2°C	[Signature]
20/11/12	4,3	672	48,2	9,2	91,2	25,1°C	[Signature]
18/12/12	4,1	756	50,7	6,4	81,6	26,6°C	[Signature]
22/01/13	5,4	612	84,3	3,7	77,8	25,3°C	[Signature]
14/02/13	4,4	629	60,1	5,4	88,4	24,1°C	[Signature]
11/03/13	6,1	721	49,2	7,5	92,1	25,1°C	[Signature]
09/04/13	4,8	512	53,1	8,7	91,1	26,2°C	[Signature]
14/05/13	6,5	718	45,2	9,2	89,4	24,0°C	[Signature]
18/06/13	7,3	628	62,4	7,4	90,1	26,1°C	[Signature]
17/07/13	4,7	604	51,2	5,7	87,4	23,0°C	[Signature]

SOP-EQUIP 010/02

Quality of Purified Water last recorded 17 July 2013



**CALCULATION** QSL No: 45/13

2 Volumetric solution:  
Molarity/Normality: 0.1M Perchloric Factor = 0.9230

EQUIVALENCE : 1 ml is equivalent to: 26.1000 mg of Guanine Sulphate

Sample Dilution Factor= 1.0000  
Stated amount= 300.0000 (mg)

$\%Content = \frac{Titre \times Factor \times Equivalence \times Sample \ dil \ factor \times Mean \ mass \ (amount \ per \ label \ claim)}{amt \ of \ sple \ used \ * \ label \ claim}$

%Content A = 101.0184  
%Content B = 106.4075  
%Content C = 106.9074  
%Content D = #DIV/0!  
%Content E = #DIV/0!  
%Content F = #DIV/0!

Mean content= 104.75 (A,B,C)      Mean content= #DIV/0! (D,E,F)  
%RSD= 3.12      %RSD= #DIV/0!  
Limit RSD

SPECIFICATIONS: BP 2009  
95.0 to 105.0% of the stated amount

CONCLUSION: Complies

Test for content shows triplicate testing and averaging of test results. Two of the results are out-of-specification, and even though the average result is within specification, the test results should not have been determined as "COMPLIES" without further testing to eliminate the potential for laboratory error.

Also: spreadsheet has not been qualified; and no limit is shown for %RSD; BP2009 is being used – why is testing not performed to current BP (BP2013)

## ANNEX H. CRITIQUE OF QSL PROPOSED LABORATORY DESIGN

*MICHAEL ANISFELD, SIAPS CONSULTANT*

### Introduction

I have been asked by Mr. Howard Masiyachengo, QSL Manager, to review the design plans (figure at the end of this section) for the new QSL to be built in association with the contemplated move of the CMS to a facility about 70 – 80 km from Windhoek. I would make the following points.

The QSL management has not prepared a User Requirement Specification (URS) detailing what specifically they want the laboratory to be, and how it is to function, stating the workload, the staffing levels, and the types of product that need to be tested. It is essential that such a document be drawn up in writing, and approved in writing by QSL management, and by NMRC management. Such a document might significantly impact the comments in this critique (e.g., if suppositories or semi-solids are to be tested, this has an impact on the QSL design plan and on the temperate storage requirements for samples).

It is only by having this document reviewed and approved prior to the start of design and construction can it be verified that the final laboratory, as built, operates according to these design criteria.

In making the comments below I assume that QSL desires to become ISO 17025, or WHO certified, and to work in accordance with WHO Good Manufacturing Practices (which also apply to quality testing laboratories). My specific comments are all geared to this assumed goal, and my comments relate to the design plan as provided by Mr. Howard Masiyachengo on January 29, 2014. The plan provided does not bear a version number, or a date, and may not be the latest version of the QSL plans.

## CRITIQUE OF QSL PROPOSED LABORATORY DESIGN

*MICHAEL ANISFELD, MSH CONSULTANT*

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General Comments.....	63
Chemistry Laboratory .....	63
Microbiology Laboratory .....	64
Medical Devices/Condom Testing.....	66
Utilities.....	66
Postscript.....	66

## CRITIQUE OF QSL PROPOSED LABORATORY DESIGN

### General Comments

- a. Access to the QSL complex should be controlled by installation of coded locks (see examples at <http://www.codelocks.co.uk/>).
- b. There is no location identified where samples are received from CMS, stored prior to testing, and logged into the laboratory management system.
- c. There does not appear to be provision of a meeting/conference room or of office/desk areas where analysts can sit and write up their test results. While such tasks could be performed at the work bench, this is not optimal as it detracts from expensive laboratory bench space.

The desk area for the microbiological staff needs to be in their area; for the chemistry staff, in their area.

- d. Quality testing laboratories should not have cooking or eating areas (kitchen) within the complex. A separate location should be provided, perhaps within the CMS.
- e. The entire complex should be provided with air conditioning such that the QSL complex is maintained between 20 °C and 25 °C. There needs to be temperature sensors located in the wet chemistry area, the instrument area, and the microbiology area. The sensors need to be linked to either alarmed chart recorders or to a computer system which sounds an alarm if the required temperature range is exceeded. It is unacceptable to use the current system of noting the temperature from the read out of the air conditioning thermostat.

### Chemistry Laboratory

- f. No provision appears to have been made for a location to store cleaning mops and tools. This area needs to have water available to prepare cleaning/disinfection solutions.
- g. The room identified as a chemical store is the logical location for a refrigerator for storing chemical standards. I am not sure of the purpose of the refrigerator shown in the instrument room.
- h. The provision of a separate weighing room is inefficient. Modern laboratory design places balances on marble slab tables at a bench on the side of the wet chemistry laboratory.
- i. While the plan shows the chemistry laboratory as divided into two areas, wet chemistry and instrument room, there is a need to divide the wet chemistry laboratory into two sections: sample preparation (for instrumental analysis) and wet chemical analysis (e.g., titration, pH testing, osmolality testing, etc.), for a total of three working areas.

- j. Hand washing of glassware, as currently performed cannot be validated as an effective cleaning method and should not be continued. Glassware washing needs to be performed in a laboratory glassware washer (see examples at <http://www.labconco.com/category/glassware-washers>).

This washer can be located in the room identified as the “wash room,” however, to comply with pharmacopoeal requirements, the final rinse of glassware needs to be performed with Purified Water (USP/BP). The Milli-Exil type device currently used in the QSL can neither provide the quantity, or the pressure, of Purified Water required for a glassware washer.

The washing room will also need to be equipped with a drier to dry the glass, and storage racks.

- k. The fume cupboards are indicated in a separate room. This is inefficient and is not how laboratories are typically designed. The fume cupboards should be located along the side wall of the sample preparation area.
- l. The counter tops are indicated as “ceramic resistant”. This is old-fashioned technology; current laboratory design uses epoxy resin surfaces. (Ceramic tiles can crack or discolor, and the grouting between surfaces is a perennial source of mold growth. A good article on bench top selection can be found at [http://www.durcon.com/page.aspx?page\\_id=70](http://www.durcon.com/page.aspx?page_id=70)).
- m. Sinks are shown on the side benches in the various areas of the chemistry laboratory. This is inefficient, and sinks should be placed at the ends of each of the island work benches. I’m not sure why the drawing shows the need for 8 sinks in the chemistry area.
- n. The floor surface should be made from welded roll PVC material.

*Comment: There is no real need for a corridor between the offices and the chemistry laboratory, or between the wet chemistry and the instrumentation area. If the entire complex was “open plan”, then air entry would be above the office areas and above the instrumentation area – and flow out through the fume hoods in the wet chemistry area.*

### **Microbiology Laboratory**

- a. Access to the microbiology complex should be controlled by installation of coded locks (see examples at <http://www.codelocks.co.uk/>), with different codes from the general access locks. Only microbiology staff should have routine access to the microbiology section of the QSL.
- b. No provision appears to have been made for a location to store clearing mops and tools. This area needs to have water available to prepare cleaning/disinfection solutions.

- c. There is a need for the addition of an extra changing room for access from the microbiology laboratory corridor to the room labeled “laminar flow room,” which really is the product testing laboratory.
- d. The microbiology section needs to be provided with HVAC (air conditioning) that meets the requirements of ISO 14644 standard – Class 5 (old US class 100,000 conditions). These conditions need to be maintained 24/7, even when the microbiology laboratory is not working.

The HVAC needs to have a pressure cascade such that air bleeds out of the laboratory as follows.

- i. Consider the general QSL corridor at no pressure differential
- ii. The airlock to enter the microbiology suite needs to be at +15 Pascal to the general QSL corridor
- iii. All offices and non-clean work areas (e.g., office and media prep) should be a +15 Pascal to the general QSL corridor
- iv. The gowning room to enter the “product testing laboratory” should be at +30 Pascal to the general QSL corridor
- v. The “product testing laboratory” should be at +15 Pascal to the general QSL corridor

These pressure differentials need to be constantly monitored and alarmed. A wall mounted Magnahelic gauge (to note pressure differential), while cheap, will not be acceptable.

- e. As you walk into the microbiology laboratory suite the sequence of rooms passed on the left side when walking along the corridor should be, in sequence:
  - i. Microbiology entry airlock
  - ii. Cleaning mops and cleaning tool storage  
(with provision of water to make cleaning and disinfection solutions)
  - iii. Garment washing and sterilizing  
(unless you intend to use single use disposable gowning, or will use a contract sterile laundry)
  - iv. Office
  - v. Dry media storage, media preparation and sterilization (needs provision of Purified Water [BP/USP]). This room also needs a sterilizer for sample decontamination
  - vi. Prepared media storage and sample incubation  
(needing refrigerators, and incubators at 25°C and 32°C)
  - vii. Air lock to change gowns prior to entry into the Product Testing Laboratory

- viii. Product Testing Laboratory needs to be equipped with biosafety cabinets (recirculating laminar flow benches)

*Note I have changed the room functions that are shown on the plan provided;— as such, the room dimensions will need to be changed to accommodate the activities described.*

- f. There needs to be a pass-through between the media preparation area and the product testing area. This pass-through is also used to remove plates test samples for incubation.
- g. The microbiologist working in the Product Testing Laboratory needs to wear a fresh sterile gown each time s/he enters this area. The current plan shows no provision for laundering and sterilizing of gowns. Shall I assume that a sterile laundry is available in Namibia, or that you will provide single-use sterile gowning?
- h. Microbiology staff need to wear a fresh overall each day; again a question of laundry capability.

### **Medical Device/Condom Testing**

no comments – looking good.

### **Utilities**

No mention is made of the provision of:

- a. Water for use in sinks, in microbiological sterilization processes (*need analysis of quantity and pressures*), and in preparation of cleaning/disinfectant solutions.
- b. Purified Water (BP/USP grade) for use in glassware final rinse and in test sample preparation for use in the chemistry laboratory and for use in media preparation in the microbiology laboratory.
- c. Lighting levels: the current QSL laboratory has inadequate lighting. Lighting needs to be a minimum of 3,000 lux.
- d. Location of gas cylinders (helium, nitrogen, etc.) for use with test equipment, and the outlets for these gases at bench level.

### **Postscript**

I question the need for QSL to relocate to the new CMS site. As QSL does not perform sample testing, and since the CMS will send stock daily to the current CMS site in Windhoek, which

will be used as a regional store, QSL will still maintain ready access to samples for testing. Additionally, senior managerial oversight of the QSL function is difficult when QSL is currently about 5 kilometers from NMRC management.– The relocation to 80km away will significantly magnify this concern about managerial oversight, to say nothing of the difficulty that will be faced in staffing the new facility with trained analysts and chemists.

