Strengthening Registration and Quality Assurance Systems for Generic ARVs, Related Medicines, and Devices in Namibia

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Strengthening Registration and Quality Assurance Systems for Generic ARVs, Related Medicines, and Devices in Namibia

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October 2014

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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure 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, dossiers, Good Manufacturing Practices, Namibia, Medicines Regulatory Council, medical equipment

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CONTENTS

ACRONYMS AND ABBREVIATIONS

3TC	lamivudine
ART	antiretroviral therapy
ARV	antiretroviral
AZT	zidovudine
CTD	common technical document
EFV	efavirenz
FTC	emtricitabine
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
MoHSS	Ministry of Health and Social Services
NMRC	National Medicines Regulatory Council
NVP	nevirapine
QSL	Quality Surveillance Laboratory
RPM Plus	Rational Pharmaceutical Management Plus
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SPS	Strengthening Pharmaceutical Systems
TB	tuberculosis
TDF	tenofovir disoproxil fumarate
UNAM	University of Namibia
USAID	United States Agency for International Development
WHO	World Health Organization

ACKNOWLEDGMENTS

The authors of this report express our gratitude to the Ministry of Health and Social Services (MoHSS) for making it possible for this work to be performed.

We are also grateful to the Registrar of Medicines, Mr. Johannes Gaeseb, and the staff of the Namibia Medicines Regulatory Council (NMRC) secretariat for the time and support provided throughout the implementation of these activities, and for the commitment to improving efficiency in the registration and quality assurance of medicines in Namibia. We owe a great debt of gratitude to them for their interest, active participation, and teamwork throughout the project. We are also grateful for the support of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) home office staff, whose technical input guided the implementation of the activities highlighted in this report.

We acknowledge the management, technical, and operations/administration staff of SIAPS in Namibia for their support in implementing the activities in this report.

SIAPS is grateful to the US Agency for International Development (USAID) for project funding that enabled the implementation of activities between October 2013 and September 2014, which formed the basis of this report.

BACKGROUND

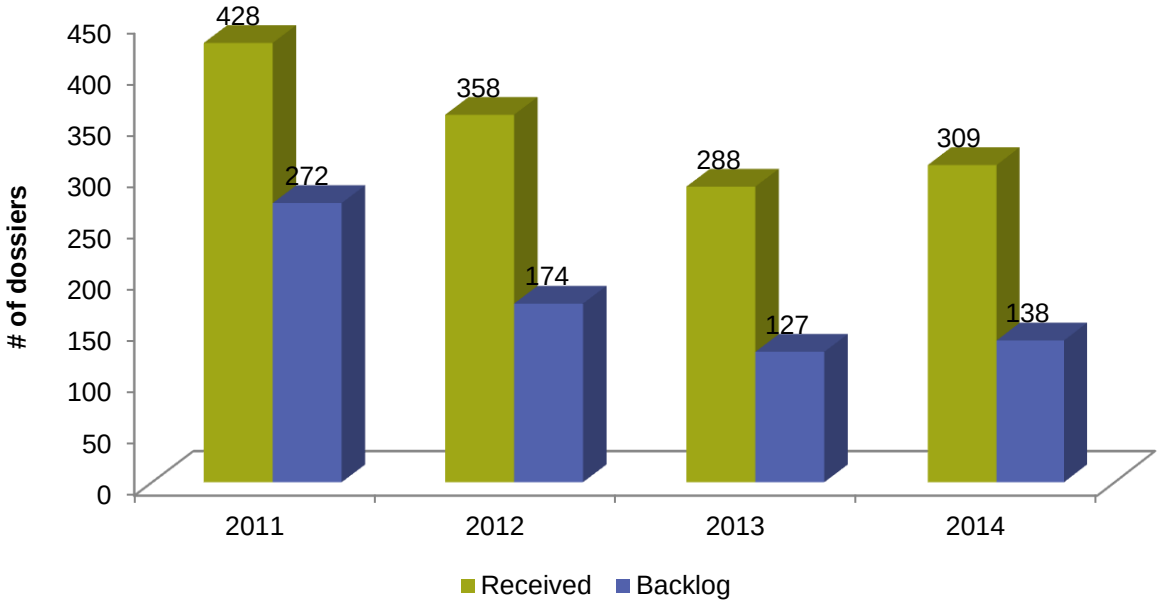
The NMRC is mandated by the Namibian Medicines and Related Substances and Control Act of 2003 to regulate and ensure access to medical products and protect public health. Under the MoHSS, Pharmaceutical Control and Inspection—a subdivision of the Pharmaceutical Services Division under the Tertiary Health Care and Clinical Support Services Directorate—is the secretariat of the NMRC.

In Namibia, USAID has been providing funding for technical assistance in the areas of pharmaceutical management and systems strengthening since 2003. During this period, the Rational Pharmaceutical Management Plus (RPM Plus) and Strengthening Pharmaceutical Systems (SPS) programs were implemented. The design of RPM Plus enabled Namibia to target innovative and effective interventions in the six functional areas of baseline assessments on policy and legal framework, selection and formulary management, procurement, distribution, appropriate use, and management support. RPM Plus supported interventions that largely focused on strengthening systems for the antiretroviral therapy (ART) and prevention of mother-to-child transmission of HIV programs. SPS focused on strengthening systems based on World Health Organization (WHO) building blocks, increasing the number of pharmaceutical personnel available for service delivery, strengthening policy coordination, and improving the regulatory functions of the NMRC. SIAPS focuses on further strengthening of regulatory and management systems in the pharmaceutical sector under the governance and health systems strategic area to support HIV and AIDS and other public health services.

Despite the efforts and achievements of previous programs and of SIAPS during its first three years, the NMRC continues to encounter human resource and technical capacity challenges that have, over the years, prevented effective pharmaceutical regulation in Namibia. In addition to these challenges and inadequate standard operating procedures to guide the operations, the agency was marred by inefficiencies in the medicine registration process (granting of market authorizations) and quality assurance mechanism that resulted in limitations and delays in the availability of new antiretroviral (ARV) medicines, including new pediatric formulations, and other essential medicines at health facilities, thereby compromising ART outcomes. The problem is reflected in the backlog of more than 700 dossiers that awaited evaluation for registration for the last five years (Anisfeld, 2014). With only two staff responsible for evaluating dossiers prior to September 2014, the NMRC is still challenged by the lack of human resources and technical capacity to evaluate medicines in a timely manner, which increased the backlog of dossiers awaiting review. In 2012, the average number of days required to register a product on a fast-track basis without full dossier review was 53.[1]

Figure 1 shows that the backlog carried over by year was 64% (272) of the received dossiers in 2011, 49% (174) in 2012, 44% (127) in 2013, and 45% (138) in September 2014. Although a decreasing trend was observed over the three years, the cumulative number of dossiers in the backlog had increased to 746 by March 2014, depicting a growth rate of more than 150 dossiers per year.

[1] Includes days from entry of data in Pharmadex to product registration. Application details are not captured in Pharmadex on submission, and the period between submission and data entry is significant.



Source: Pharmadex database

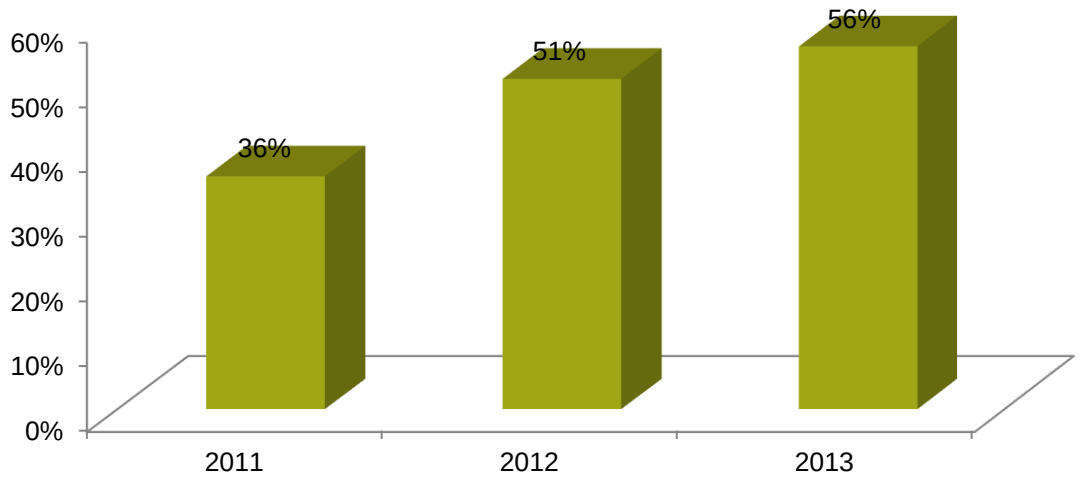
Figure 1. Received and unevaluated/backlog dossier applications at NMRC, 2011–2014

ARV formulations comprised 3.08% of the backlog (table 1). The products included newly optimized fixed dose combination formulations, EFV/FTC/TDF tablets for adults, and 3TC/AZT and 3TC/NVP/AZT dispersible tablets for pediatric use.

Table 1. Number of ARV Formulations in the Dossier Backlog, 2010–March 2014

Year	Adult	Pediatric	% of backlog
2010	1	0	0.13%
2011	4	0	0.54%
2012	4	1	0.67%
2013	9	2	1.47%
2014	1	1	0.27%
Total	**19**	**4**	**3.08%**

In previous years, SIAPS contributed to improving the efficiency of the medicine registration process despite challenges at the NMRC. With support from SIAPS, there has been an improvement in the proportion of dossiers for medicines registration evaluated annually (figure 2). The proportion of dossier applications evaluated against those received has been increasing since 2011.



Source: Medicine registration database, Pharmadex. Namibia MoHSS, March 2014.

Figure 2. Percentage of dossiers evaluated against those received by the NMRC

In addition to challenges in the medicines registration function, the lack of human resource and technical capacity significantly affects the performance of other regulatory functions (i.e., the Therapeutics Information and Pharmacovigilance Center, which provides medicine usage warnings and advice to Namibian health care providers and monitors adverse drug events for patient safety; Good Manufacturing Practices (GMP) inspections and licensing of pharmacies, clinics, hospitals, and wholesalers; and the Quality Surveillance Laboratory (QSL), which is responsible for testing samples of medical products received by the Central Medical Store as well as postmarket surveillance of medicines samples received from different locations within Namibia). Moreover, inadequate pharmaceutical regulation poses a risk that substandard and counterfeit pharmaceuticals that may negatively affect treatment outcomes for HIV and AIDS, tuberculosis (TB), and other diseases may be circulated.

As of October 2013, the MoHSS did not have an adequate system for regulating medical equipment and devices that are marketed and used in Namibia. This poses a challenge to health care providers and a potential risk to patients if a given piece of medical equipment or a device is unknowingly defective or malfunctions without the knowledge of the user. The MoHSS was also challenged by limited technical capacity to manage medical equipment, ensure its effective and optimal use, and improve the quality of HIV and AIDS health care delivered at health care facilities. The National Healthcare Technology policy was last published in 2003, and there was a need to update and align the medical equipment policy with the latest medical technology. There was also a need to develop a comprehensive list of essential medical equipment for all health care facility levels to provide quality HIV and AIDS health care services in all public-sector health facilities in Namibia. In a country faced with a significant burden of HIV and AIDS, TB, and other infectious diseases that necessitate the use of various types of medical equipment and devices in health care delivery, it is imperative that a strong and robust regulatory system for this category of products is in place. Such a system includes product evaluation and registration, registration and licensing of suppliers, inspection of the distribution channel and other postmarketing activities, and certification or licensing of users and technicians responsible for the repair and maintenance of such equipment.

INTERVENTIONS

Review of NMRC Operations

In 2014, the USAID-funded SIAPS Program, implemented by Management Sciences for Health, conducted a review of NMRC operations to identify the gaps and challenges in its operations and propose recommendations to improve the efficiency of the NMRC and ensure expedited registration of quality, safe, and efficacious generic ARVs, including optimized pediatric formulations; other essential medicines; and medical devices to improve the availability of quality and safe ART commodities, thereby improving patient treatment outcomes and prolonging life. A holistic follow-up review of the NMRC was conducted to determine progress during SPS and 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 ARVs and other essential pharmaceuticals. In-depth discussions were held with the technical staff of the NMRC secretariat and documents were reviewed to identify goals from the 2009 plan that had been met; gain a better understanding of the roles and responsibilities of the NMRC; and provide recommendations on how to improve the efficiency of the NMRC's operations, which were documented in the consultant's report (Anisfeld, 2014) and shared with NMRC staff.

An analysis of data on timelines for medicine registration in Namibia was conducted for 2013. Pharmadex, which was developed by SPS, was the source of the data. The analysis was to determine the average number of days it takes the NMRC to process an application for medicines registration and the number of applications that had not been processed between 2010 and March 2014.

Building the Technical Capacity of In-country Pharmaceutical Personnel and Institutions for Medicines Regulatory Practices

A gap analysis conducted in January 2014 with technical assistance from SIAPS to improve and strengthen regulatory systems in Namibia determined that the NMRC had inadequate human and technical capacity to efficiently and effectively perform its mandated functions. The findings of the gap analysis were used to define training needs for the evaluation of medicines registration dossiers, pharmaceutical Good Distribution Practices (GDP), and GMP.

In May 2014, NMRC technical staff and non-NMRC staff (e.g., MoHSS regional pharmacists, pharmacists from the University of Namibia (UNAM) School of Pharmacy, and pharmacists from the private sector) were trained on medicine dossier review practices, including the globally accepted common technical document (CTD) format and other regulatory aspects of GMP and GDP.

The main objective was to build capacity and increase the pool of personnel with technical expertise in regulatory affairs, who may be called upon to assist the NMRC with dossier evaluation as needed.

SIAPS provided technical assistance in the form of mentoring and ongoing on-the-job training to NMRC staff and other personnel engaged in evaluating dossiers for the

registration of ARVs, including new pediatric formulations and other essential medicines. The training was conducted in May 2014 during organized dossier evaluation sessions to further enhance the dossier evaluation skills of NMRC staff and other health care personnel.

SIAPS also supported the NMRC to leverage appropriate information technology by upgrading Pharmadex to a web-based version, which could accommodate other functions in the NMRC and enable online application submissions and processing to enhance efficiency. These upgrades will enable close monitoring and faster processing of registration applications for pharmaceutical products and allow informed decisions to be made in a timely manner.

SIAPS continued to provide technical support to the NMRC to develop a guide for conducting medicines quality monitoring in the country as part of the postmarket surveillance initiative for quality ARVs, which SIAPS supported the Pharmaceutical Control & Inspection to establish in program year 2. Following the completion of the guide, a protocol for a baseline medicines quality assessment was developed and implemented by the NMRC to collect samples from different parts of the country, which were tested by the QSL. This would ensure that only quality, safe, and efficacious pharmaceutical products are available for use in Namibia. Three QSL staff were also trained in GMP for pharmaceuticals quality control laboratories in May 2014.

Medical Equipment Management

SIAPS provided technical assistance to the MoHSS to strengthen the management and regulation of medical devices and support equipment in Namibia. This involved updating the National Healthcare Technology policy and developing a comprehensive list of essential medical equipment for each level of public health facility.

Figure 3. Participants at a hands-on dossier review session. May 2014, Windhoek (Photo credit: SIAPS/Namibia staff)

RESULTS/OUTCOMES

General Operations of NMRC

The review of NMRC operations highlighted an insufficient number of human resources for the medicines dossier evaluation work load. The NMRC utilized the report to recruit additional staff. Three pharmacists were recruited in September 2014 to work in the registration section, increasing the number of dossier reviewers to five. The review also highlighted the technical capacity of staff involved in dossier review, and this finding informed the training that SIAPS supported the NMRC to conduct in May 2014.

Strengthened Human and Technical Capacity for Medicine Registration

In agreement with the Permanent Secretary of the MoHSS, SIAPS supported the MoHSS/NMRC by training 42 pharmaceutical personnel, including NMRC staff, UNAM School of Pharmacy lecturers, MoHSS pharmacists, and private pharmacists, to increase the pool of dossier reviewers in the country. The trainees were also exposed to other aspects of medicines regulation, including GDP and GMP. The approach of intensive dossier evaluation sessions was embraced by the MoHSS, where pharmacists came together to review dossiers as a team to reduce the backlog and further improve their dossier evaluation skills. In line with the MoHSS 2013 pharmaceutical services retreat recommendation for the NMRC to engage private-sector pharmacist to assist with the backlog, 33% of the trainees were from that sector. SIAPS also provided support in the development of the NMRC medicines evaluation consultancy services contract, which is currently under consideration by the MoHSS. UNAM School of Pharmacy lecturers comprised 17% of the trainees, and will pass on their knowledge to bachelor of pharmacy students as part of the sustainability strategy.

In July 2014, 23.8% of the personnel who had been trained gathered for a group dossier evaluation session in Windhoek. Using the dossier screening and technical evaluation approaches and applying the acquired knowledge and skills, they reduced the backlog reported in March 2014 by 16.7%. This included applications received in 2010 and part of 2011.

Table 2. Medicine Dossiers Assessed in the July 2014 Session

#	Categories	Numbers
Applications that passed screening		
1	Evaluated	30
2	Not evaluated	10
Applications that failed screening		83
Total		**123**

Postmarket Surveillance

In FY14, SIAPS supported the NMRC to develop a medicines quality monitoring guide, which was accepted and is being used to guide postmarket surveillance activities in Namibia. Three QSL staff were trained in GMP for quality control laboratories, which improved local

technical skills to manage the laboratory in accordance with WHO prequalification requirements and test postmarket surveillance samples for the purpose of monitoring the quality of medicines in the country.

Pharmadex

In February 2014, SIAPS demonstrated to NMRC technical staff the prototype version of the web-based Pharmadex tool and obtained input from users for further customization and enhancement of the tool to optimize its functionality. The tool was redesigned, personnel were trained, and data were migrated from the old version to the upgraded version and tested by NMRC users. The NMRC website was redesigned and the medicine register generated by Pharmadex would be available online as recommended during the 2013 MoHSS pharmaceutical services retreat (figure 4). The tool, once fully operationalized, will also relieve NMRC staff of the task of entering data on medicines applications, as this will be done directly by applicants, and NMRC staff efforts will be directed toward technical evaluations to expedite the medicines registration process.

Figure 4. The NMRC website and redesigned, web-based Pharmadex (July 2014)

Annual Medicines Registration by the NMRC

As a result of continued technical assistance to and mentoring of NMRC staff on dossier evaluation, significant improvements were made in the medicines registration process. The average number of days needed to register a product decreased from 53 in 2013 to fewer than 34 in 2014, and the number of registered pharmaceutical products increased by 630 (table 3) to a total of 5,922 as of September 2014. The ARVs registered in FY14 represent a significant portion of the ARVs that formed the backlog and included fixed dose combination products that were recommended as first-line ARVs in the 2014 revision of the Namibia ART guidelines.

Table 3. Annual Summary of Medicines Registration by the NMRC with SIAPS Support

Registration Session	# of products registered	# ARVs registered
April 2014	44	4
July 2014	533	5
September 2014	53	4
Total	**630**	**13**

Strengthening the Medical Devices and Support Equipment System in the Public Sector

SIAPS supported the MoHSS to conduct consultative meetings with key stakeholders at referral and intermediate hospitals to guide the National Healthcare Technology Policy update and develop comprehensive lists of medical equipment essential for quality health care service delivery in public health facilities at different levels in support of HIV and AIDS management in Namibia. The list for lower-level health facilities was completed and the drafts for the policy and upper-level health facilities are under review.

Figure 5. Ms. Belinda Wobling, the MoHSS Chief Medical Engineer, gave introductory remarks during the essential medical equipment consultative meeting at Intermediate Hospital Oshakati, Namibia, in September 2014 (Photo credit: SIAPS/Namibia staff)

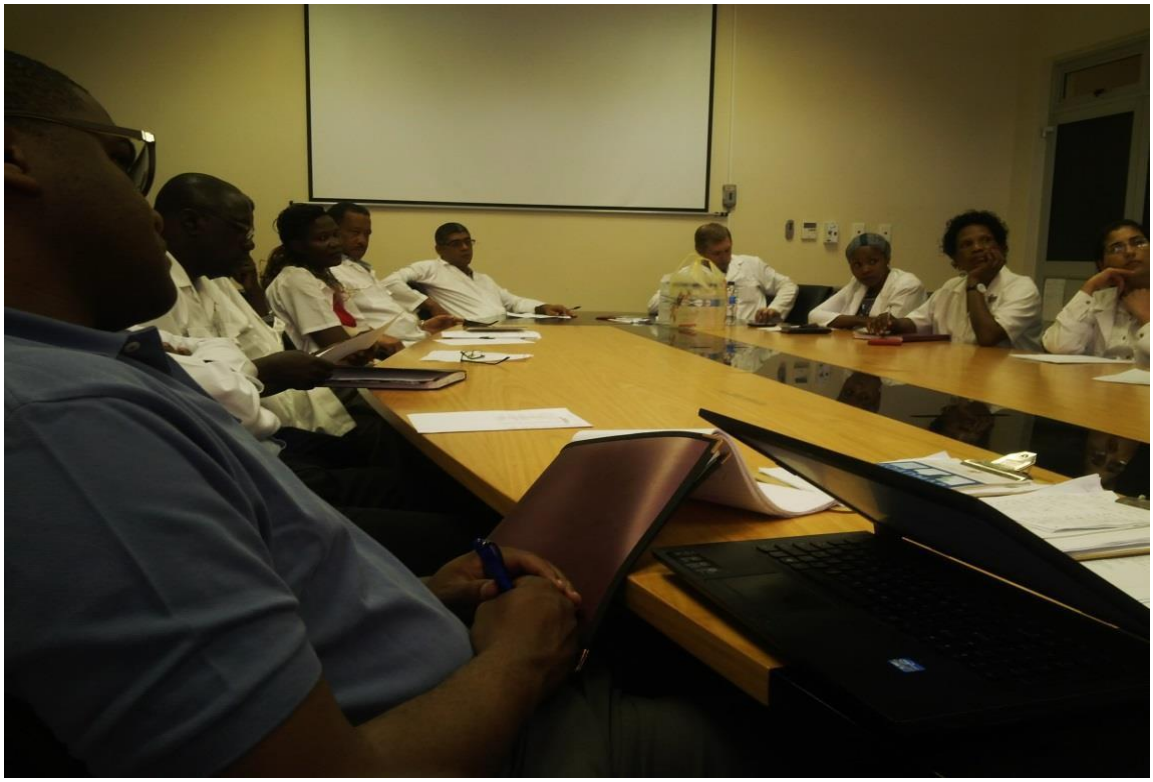


Figure 6. Intermediate Hospital Oshakati department heads at the essential medical equipment consultative meeting, September 17, 2014 (Photo credit: SIAPS/Namibia staff)

CONCLUSIONS

The capacity of the pharmaceutical regulatory system in Namibia was enhanced, and improvements in the efficiency of the NMRC were noted. The total number of products registered increased by 12% from 2012 to 2013, and the number of dossiers pending evaluation decreased by more than 16% during the same period. Great strides were made to conduct medicines quality postmarket surveillance activities. Pharmadex was upgraded to a web-based version, and documented tools for managing medical equipment were put in place. This was attributed to SIAPS' continued technical support in building personnel and institutional capacity.

Figure 7. Participants at the dossier evaluation training workshop, May 12–16, 2014, Windhoek (Photo credit: SIAPS/Namibia staff)

REFERENCES

Anisfeld M, An L, Mbaziira N, Kagoya H, Sagwa E. 2014. Strengthening the Capacity of the Namibia Medicines Regulatory Council in the Regulation of Antiretroviral Medicines and Other Essential Pharmaceuticals. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health

Namibian Medicines and Related Substances and Control Act of 2003

National Guidelines for Antiretroviral Therapy, fourth Edition, January 2014, MoHSS, Namibia

Systems for Improved Access to Pharmaceuticals and Services Namibia Work Plan: October 1, 2013–September 30, 2014

ANNEX A. GMP TRAINING PARTICIPANTS

No.	Name	Gender	Designation	Duty Station
Facilitators				
1	Michael H. Anisfeld	M	SIAPS consultant	TDY-Windhoek
2	Pascal Rite	M	Registration pharmacist	NMRC-Windhoek
3	Nasser Mbaziira	M	Senior technical advisor	SIAPS-Windhoek
Trainees				
1	Mr. Nelson Olabanji	M	Regional pharmacist	Swakopmund Health Directorate
2	Mr. Msafiri F. Kweba	M	Regional pharmacist	Oshakati
3	Mrs. Grace Adeniy	F	Regional pharmacist	Katima Mulilo
4	Mr. Norbert Marealle	M	Regional pharmacist	Okahandja
5	Mr. Ahmad Zaman	M	Regional pharmacist	Opuwo Hospital
6	Mrs. Girlie Madyara	F	Pharmacist	St. Mary Rehoboth Hospital
7	Mr. Augustine Odo	M	Regional pharmacist	Outapi
8	Mr. Tafadzwa Marimo	M	Pharmacist	Keetmanshoop
9	Mrs. Hilkka Udjombala	F	Pharmacist	NMRC
10	Dr. Diethardt Rodenwoldt	M	Veterinarian	Swakopmund Veterinary Clinic
11	Ms. Rosemary Ehiemua	F	Pharmacist	Ohangwena Hospital
12	Mr. Louis Prins	M	Pharmacist	Nampharm
13	Ms. Erlene Van Aerde	F	Pharmacist	Medi Park Pharmaceutical
14	Mr. Paulus Mwandingi	M	Pharmacist	Private consultant
15	Mr. Qamar Niaz	M	Pharmacist	NMPC
16	Mr. Evans Sagwa	M	Pharmacist	SIAPS
17	Mr. Alemayehu Wolde	M	Pharmacist	SIAPS
18	Ms. Harriet Kagoya	F	Other health worker	SIAPS
19	Ms. Fiona Mbai	F	Pharmacist	Blue Shark
20	Mr. Johannes Gaeseb	M	Pharmacist	NMRC-Secretariat
21	Mr. Gilbert Habimana	M	Pharmacist	NMRC-Secretariat
22	Mr. Ruigi Njiriri	M	Pharmacist	NMRC-Secretariat
23	Ms. Saren Kauhondamwa	F	Pharmacist	NMRC-Secretariat
24	Mr. Howard Masiyachengo	M	Pharmacist	NMRC-QSL
25	Mrs. Laydia Hamalwa	F	Other health worker	NMRC-QSL
26	Mr. Zedekias Tjiho	M	Other health worker	NMRC-QSL
27	Mr. Ulrich Ritter	M	Pharmacist	NMRC
28	Mr. Albie Jordan	M	Pharmacist	Fabupharm
29	Ms. Ronelda Dewitt	F	Other health worker	Fabupharm
30	Mr. Fanie Badenhart	M	Pharmacist	Fabupharm
31	Mr. Benjamin Ongeri	M	Pharmacist	SCMS
32	Ms. Mariza Titus	F	Other health worker	IntraHealth
33	Ms. Elizabeth Ohandi	F	Other health worker	Abt Associates
34	Mr. Seth Nowaseb	M	Pharmacologist	UNAM School of Pharmacy
35	Dr. Michael Knott	M	Pharmacist	UNAM School of Pharmacy
36	Ms. Ester Naikaku	F	Pharmacist	UNAM School of Pharmacy
37	Mr. Dan Kibuule	M	Pharmacist	UNAM School of Pharmacy
38	Mr. Anthony Ishola	M	Other health worker	UNAM School of Pharmacy
39	Ms. Klaudia Amakali	F	Other health worker	UNAM School of Pharmacy
40	Mr. Bonifasius Sinqu	M	Pharmacist	UNAM School of Pharmacy
41	Ms. Helena Ndakolonkoshi	F	Pharmacist	Central Medical Store
42	Ms. Ester N. Mvula	F	Pharmacist	Central Medical Store
43	Ms. Rakel Mbanqo	F	Pharmacist	Central Medical Store
44	Ms. S. Nakamhela	F	Pharmacist	Central Medical Store
45	Ms. Elina Veigo	F	Pharmacist	Erongo MED
46	Ms. Sandra Kapinuga	F	Other health worker	Erongo MED
47	Ms. Kudakwashe Chikomwe	F	Pharmacist assistant	Eronqo MED
48	Ms. Coetzee Bernadia	F	Pharmacist	Pharmaceutical Society of Namibia
49	Mr. Cosma Mukaratrua	M	Pharmacist	Erongo MED
50	Ms. Marreli Fourie	M	Pharmacist	NMRC

ANNEX B. OFFICIAL INVITATION LETTER FOR PARTICIPANTS

9 - 0/0001

REPUBLIC OF NAMIBIA

Ministry of Health and Social Services

Private Bag 13366
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Windhoek

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Telefax: (061) 225 048
International: 264 - 61 – 203 2403

OFFICE OF THE PERMANENT SECRETARY

Ref. No. : 10/1
Enquiries: Johannes Gaeseb

Date: 09 April 2014

TO: ALL REGIONAL DIRECTORS

RE: INVITATION OF ALL REGIONAL PHARMACISTS TO THE TRAINING ON REGISTRATION APPLICATION DOSSIER EVALUATION, CURRENT GOOD MANUFACTURING PRACTICES (cGMP) AND GOOD DISTRIBUTION PRACTICES (GDP), WINDHOEK, 12 – 16 MAY 2014.

In collaboration with the MoHSS's development partner MSH/SIAPS, the Namibia Medicines Regulatory Council (NMRC) is organising training on the topics mentioned below. Essentially the training will be on how to submit medicines registration applications in the Common Technical Document (CTD) format and the review of these registration application dossiers. This is another effort to build capacity in this area which is essential to ensure availability of quality medicines in the country.

The training schedule is as follows:

Session one - CTD Format: 12 – 14 May 2014

Session two - cGMP: 15 May 2014

Session three - GDP: 16 May 2014

"Health for All"

I wish to request you to release your regional pharmacist to attend the training detailed above. The expenses for accommodation and meals will be covered and you are only requested to provide transport.

Please submit your nominations before or on 25th April 2014 preferably by e-mail to: Ms. Saren Kauhondamua, e-mail: drugreg@nmrc.com.na, Tel: 061 2032402, Fax: 061 225 048.

Yours Sincerely,

25 APR 2014

ANDREW NDISHISHI (MR)
PERMANENT SECRETARY