Volume 6, Issue 1, Oct-Dec 2023

KNOW YOUR MEDICINES
THERAPEUTIC INFORMATION AND PHARMACOVIGILANCE CENTRE

THE NAMIBIA

MEDICINES WATCH

Republic of Namibia
Ministry of Health and Social Services

UPDATE FOR HEALTHCARE PROVIDERS

QUARTERLY PUBLICATION OF THE THERAPEUTICS INFORMATION AND PHARMACOVIGILANCE CENTRE (TIPC) OF THE NAMIBIA MEDICINES REGULATORY COUNCIL (NMRC)

Your Comprehensive Resource for Adverse Events, COVID-19 Updates, and NMRC Developments

Namibia Medicines Regulatory Council
NMRC

In this issue

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EDITORIAL POLICY

The Namibia Medicines Watch is a specialised periodical providing comparative data on medications and conveying information pertaining to local and global initiatives aimed at improving the availability of information for the advancement of medication safety and responsible utilisation. All articles featured in The Namibia Medicines Watch must be relevant to healthcare sectors, including both public and private, within Namibia. Operating independently, this publication receives no support or sponsorship from local or international pharmaceutical companies. Its primary objective is to provide information that can enhance patient care and safety. The editorial team and other prominent contributors to the publication are obligated to fully disclosing any conflicts of interest.

Acknowledgement

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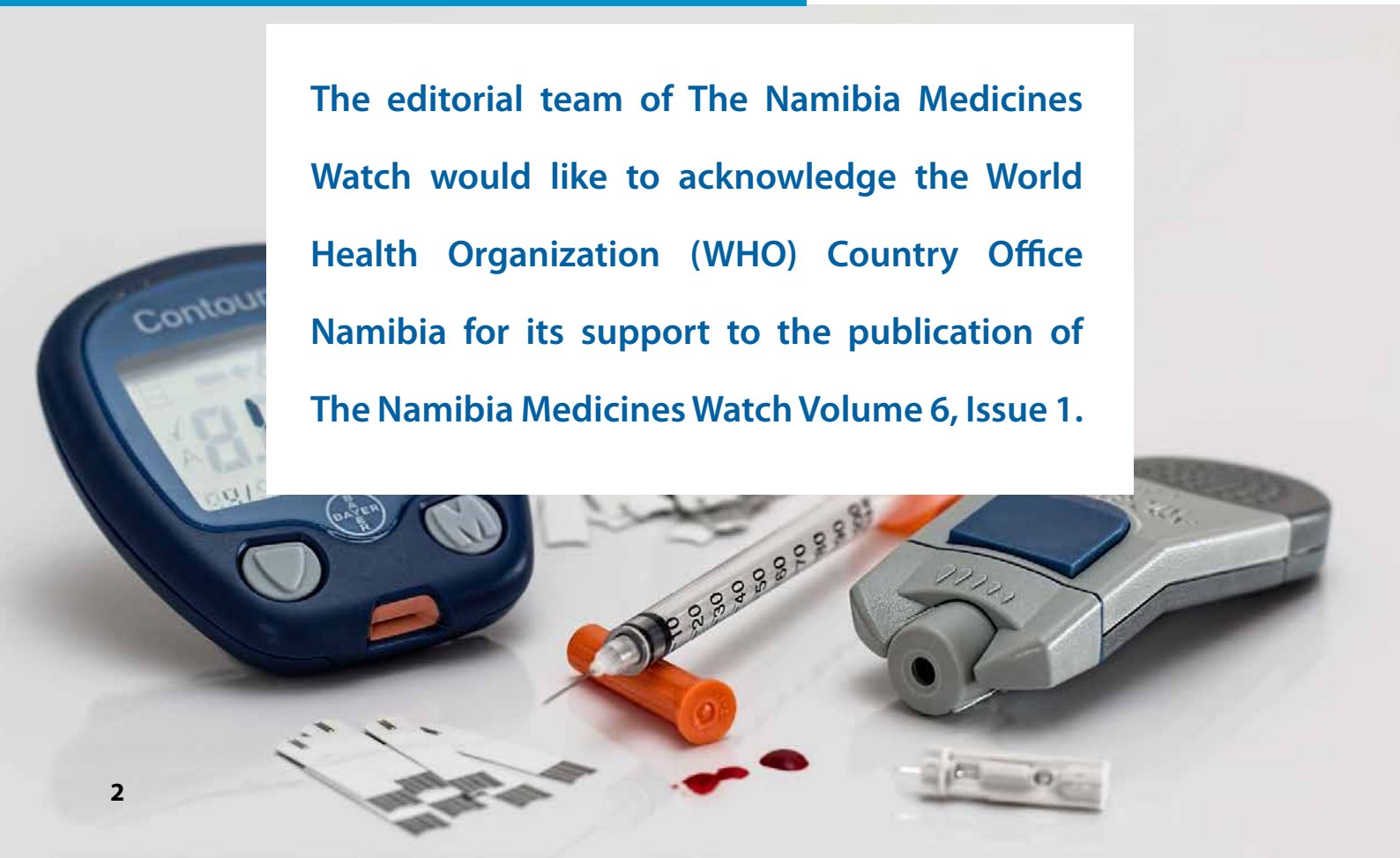

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CONTENT

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MINISTER APPOINTS
THE 5TH NMRC

Anna Shimbulu / Nadine Mouton

NMRC Secretariat

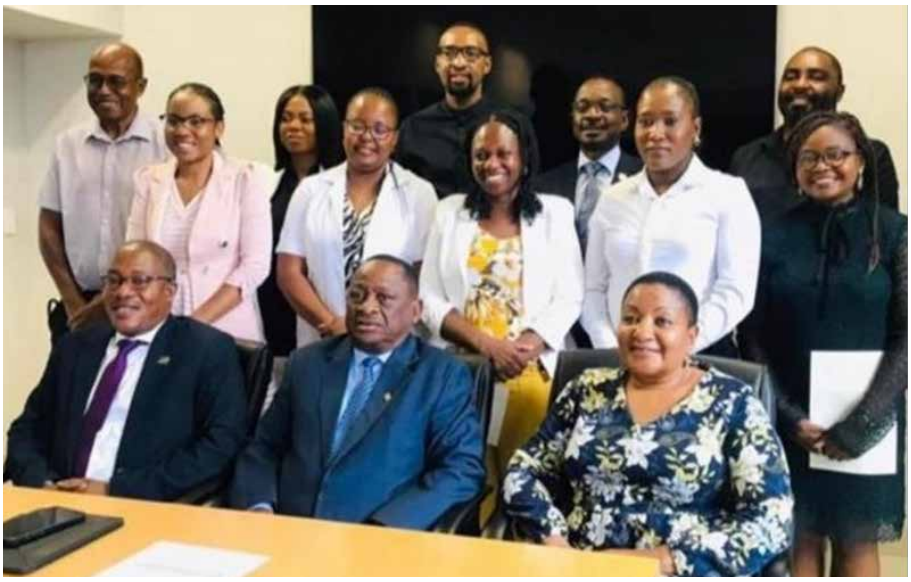
The Minister of Health and Social Services officially appointed and inaugurated the 5th Namibia Medicine Regulatory Council (NMRC) on 17 April 2023.

The Council is chaired by Dr. Ishmael Katjitae, with Ms. Grace Nakalondo serving as the deputy chairperson. Additional members of the 5th Council include Mr. Barnabas Iitula, Ms. Belinda Tsauses, Dr. Lorraine Ndjoze, Dr. Martha Shiyanga, Dr. Natangwe Amuthenu, Dr. Richard Milinga, Ms. Esther Ambunda, Mr. Mathias Kashindi, Dr. Minty Soni and Ms. Tonata Enkara.

As per the Medicines and Related Substances Control Act (Act No. 13 of 2003), the Council should consist of 12 members, as follows:

- Three (3) pharmacists
- Three (3) medical practitioners
- Two (2) veterinarians nominated for appointment by the Minister of Agriculture
- One (1) legal practitioner nominated for appointment by the Minister of Justice
- One (1) practitioner who, in the opinion of the Minister, has sufficient knowledge on medicines and related substances
- One (1) registered nurse
- One (1) other person

During his inaugural address, the Minister encouraged the Council to diligently uphold the safety, efficacy and quality of medicines. He outlined a series of crucial priorities that span a spectrum of healthcare concerns, urging concerted efforts to address them during their tenure.



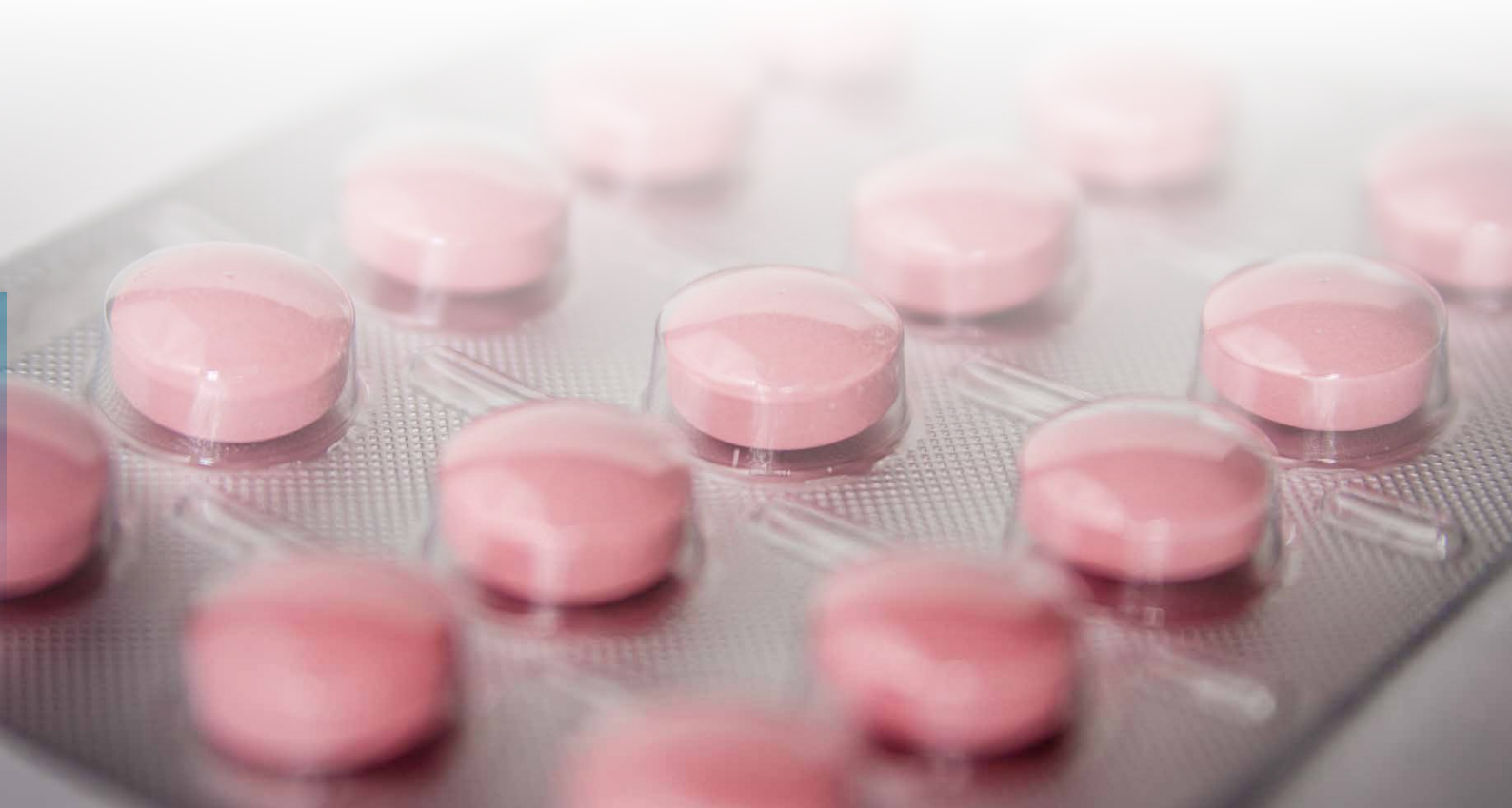
Some the Council members alongside the Ministry of Health and Social Service's Executive Director – Mr. Ben Nangombe, the Minister – Dr. Kalumbi Shangula, and Deputy Minister – Dr. Esther Muinjangue, during the inaugural meeting

The Minister stressed the urgent need to streamline the availability of medicines, eliminating any distribution delays while prioritising public safety.

The second priority placed a strong emphasis on protecting individuals from substandard and counterfeit medications through the implementation of stringent quality control measures. Strengthening the national regulatory framework emerged as a central theme, highlighting the crucial need to establish robust oversight and safety standards.

Acknowledging the interconnection between veterinary medicines and agriculture, the Minister advocated for a comprehensive approach to address these interconnected sectors. Collaboration was another pivotal element, promoting a holistic strategy for the advancement of healthcare. Additionally, the Minister urged the Council to prioritise investments in research, positioning the healthcare sector at the forefront of medical advancements. Supporting local production of medicines was deemed vital to enhance self-sufficiency, while transitioning from outdated manual systems to digital platforms was encouraged to improve operational efficiency.

Addressing the backlog of unregistered medicines emerged as another priority, further contributing to the safety and accessibility of essential healthcare products. Lastly, the Minister encouraged the members to be prepared to respond swiftly in their operations whilst upholding the law.



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NEW MEMBERS OF THE COUNCIL

Dr. Ismael Katjitae

Qualifications: German MBCHB equivalent

M. Med (Int.) Stell

Designation: Specialist Physician (in state and private sector)

Ms. Grace P Nakalondo

Qualifications: BPharm (Hons) - UWC

Designation: Pharmacist

Mr. Shanghala Kashindi

Qualifications: : LLM International Law, Admitted Legal Practitioner of the High Court of Namibia

Designation: Chief: Law Reform Services

Dr. Martha Ndeshipanda Shiyanga

Qualifications: Bachelor of Medicine and Bachelor of Surgery (MBChB)

Designation: General Practitioner

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Dr. Lorraine Ndjoze

Qualifications: MBChB (Stellenbosch), DCH (CMSA), Fellowship Paediatrics (CMSA), PEM (Edinburgh)

Designation: Senior Specialist – Paediatrician, Head of Department - Paediatric, Windhoek Central Hospital

Ms. Belinda Roselin Tsause

Qualifications: PhD Candidate, MPhil HIV/AIDS Mgt., PDM: HIV/AIDS Mgt., B. Degree: Biomedical Technology, ND: Biomedical Technology, Cert. Pharmacovigilance

Designation: Lecturer: Biomedical Sciences

Ms. Tonata Enkara

Qualifications: BPharm (Hons) - Rhodes; MBA (management strategy) - UNAM; Certificate in Transformative Leadership (ALI)

Designation: Pharmacist; Lecturer

Mr. Barnabas S. Iitula

Qualifications: B. Pharm (Hons) UWC, MClinPharm (Ongoing) UNAM

Designation: Acting Deputy Director, Operations Division (Central Medical Stores), Directorate of Pharmaceutical Services

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Dr. Richard Milinga

Qualifications: Bachelor of Science (BSc)/Bachelor of Medicine and Surgery (MBChB)

Designation: General Practitioner

Ms. Ester Shambekela Ambunda

Qualifications: Bachelor of Nursing Science (UNAM), Post Graduate Diploma in Critical Child Care (UCT), Post Graduate Certificate in Cardio-oncology (Technological University, Spain), Post Graduate Diploma in Paediatric and Adolescent Cardiology and Cardiac Catheterization (Technological University, Spain), Master in Nursing Science (International University of Management)

Designation: Senior Registered Nurse at Paediatric Intensive Care Unit, Windhoek Central Hospital

Dr. Natangwe Amuthenu

Designation: Deputy Chief Veterinary Officer (Ministry of Agriculture, Water and Land Reform)

Dr. Minty Soni

Qualifications: Bachelor of Veterinary Medicine

Designation: Veterinary Surgeon, Rhino Park Veterinary Clinic

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NMRC SECRETARIAT – NEW STAFF

New members of the NMRC Secretariat

Health Programme Officer (Laboratory Analyst)

Mr. Pombili P.N Kambwali

Bachelor of Pharmaceutical Engineering, (Honours) Degree

Health Programme Officer (Laboratory Analyst)

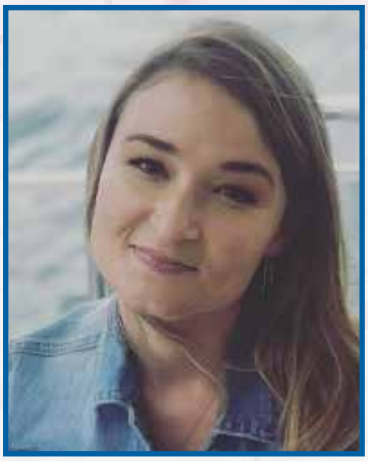
Mr. Simaneka I. Fabian

Bachelor of Science Chemistry Major Mathematics Minor

Health Programme Officer (Laboratory Analyst)

Ms. Lavinia N. Ruben

Bachelor of Science Chemistry Major Biology Minor



Inspection and Licensing Pharmacist

Mrs. Stephanie Freygang

Bachelor of Pharmacy (Honours) Degree

Regulatory Affairs Pharmacist

Ms. Chanel Besser

Bachelor of Pharmacy (Honours) Degree

Regulatory Affairs Pharmacist

Mrs. Rahl-Jeanne Cloete

Bachelor of Pharmacy (Honours) Degree

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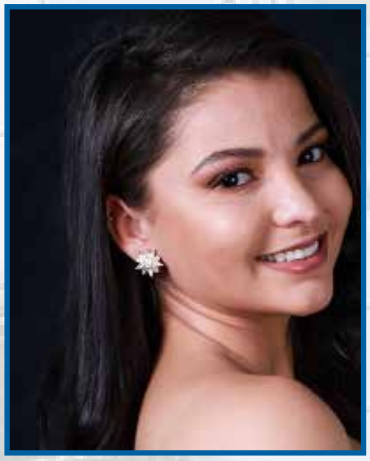


Medicines Information and Safety Pharmacist

Ms. Chelsea Moller

Bachelor of Pharmacy (Honours) Degree

Vaccine Safety Pharmacist

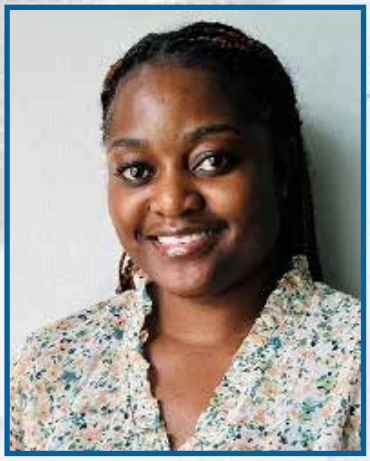
Ms. Pia Simeon

Bachelor of Pharmacy (Honours) Degree, Master of Pharmacy (Clinical Pharmacy)

TIPC – Administrative Officer

Mrs. Helena Shaningwa

Diploma in Office Administration



Regulatory Affairs Pharmacist

Ms. Karin Kamati

Bachelor of Pharmacy (Honours) Degree, Diploma in Pharmacy, Certificate in Pharmacy

Inspection and Licensing Pharmacist

Mr. Lazarus Kalisto

Bachelor of Pharmacy (Honours) Degree

Inspection and Licensing Pharmacist

Mr. Solly T. Angala

Bachelor of Pharmacy (Honours) Degree

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Regulatory Affairs Pharmacist

Ms. Justice Sheehama

Bachelor of Pharmacy (Honours) Degree, Master of Public Health in Health Services, Policies, and Management

Medicines Information and Safety Pharmacist

Ms. Eunice M Heitha

Master of Science in Pharmacy (Msc. Pharm)

Inspection and Licensing Pharmacist

Mr. Jason Bok

Bachelor of Pharmacy (Honours) Degree

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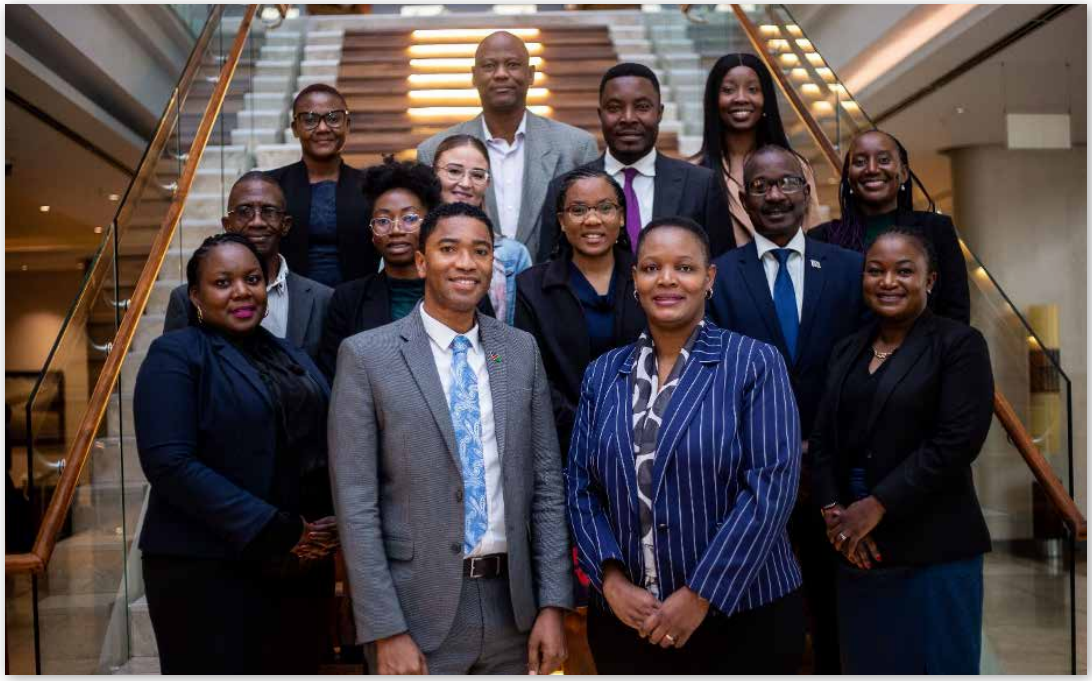
The NMRC Begins the Roadmap to Amend the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003)



Representatives from AUDA-NEPAD and Namibia at the consultative meeting

Anna Shimbulu / Fransina Nambahu NMRC Secretariat

The Namibia Medicines Regulatory Council (NMRC) in collaboration with the African Medicines Regulation Harmonization Initiative (AMRH), and the Policy and Regulatory Reforms office of the African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD), recently conducted a consultative meeting to develop the roadmap for the review and domestication of the African Union Model Law on Medical Products Regulation in Namibia. The African Union Model Law on Medical Products Regulation (AU Model Law) was adopted in January 2016 during the Twenty-Sixth Ordinary Session of Heads of State and Government of the African Union held in Addis Ababa, Ethiopia.

The Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) is the primary legislation in Namibia that governs the regulation and control of medicines and related substances within the country. The Act establishes the legal framework for the registration, importation, manufacturing, distribution, and control of medical products, including pharmaceuticals, medical devices and other healthcare-related substances.

Analysis conducted by the SADC Medicines Regulatory Harmonization (MRH) Consultants, and corroborated by the Africa Medicines Regulatory Harmonization (AMRH) Team revealed several gaps in the Act, pointing towards suboptimal regulatory conditions. These identified gaps encompass areas such as clinical trial oversight, mutual recognition, and blood and blood products. Additionally, the analysis highlighted the necessity to enhance the

articulation of provisions regarding substandard and falsified medical products, incorporating strategies as provided for in the 2nd Edition Namibia National Medicines Policy Document.

Namibia's concrete action towards improving its legislative and policy frameworks to regulate medical products provides a comprehensive blueprint and dedication to improve access to medical products that are safe, efficacious, and of assured quality.

The meeting was officiated by Dr. Theo-Ben Kandetu (Deputy Executive Director - Ministry of Health and Social Services) representing Ms. Petronella Masabane (Deputy Executive Director - Ministry of Health and Social Services). Mrs. Chimwemwe Chamdimba, AMRH Programme Head at the AUDA-NEPAD, delivered the opening remarks on behalf of AUDA-NEPAD, outlining the meeting objectives.

Local participants comprised representatives from the NMRC membership, the Ministry of Health and Social Services (Legal Office, Pharmaceutical Services and Policy and Planning Directorates), the Ministry of Justice (Law Reform and Legislative Drafting Directorates), the Office of the Attorney General, and the WHO Country Office.

The prospect of initiating a review of the medicines regulation legislative framework holds significant promise for the healthcare regulatory landscape in our country. The endeavour to update and refine this legislation, particularly in alignment with the provisions of the National Medicines Policy and other international regulatory harmonisation initiatives, can herald a new era of accelerated review and registration, leading to improved accessibility of quality and safe medical products within our healthcare system. Such an initiative will also address emerging challenges in the pharmaceutical sector, ultimately providing an opportunity for a robust Medical Products National Regulatory System. By doing so, Namibia can better safeguard the health and well-being of its citizens and foster innovation and compliance in the medical industry.

As we proceed with this initiative, we will persist in cultivating the opportunities facilitated by collaborative engagement with all stakeholders, including government authorities, healthcare professionals, and the pharmaceutical industry. This sets the stage for a more resilient and responsive healthcare system.

Participants outlining the key steps needed to domesticate the AU Model Law

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World Patient Safety Day (WPSD) – 17 September 2022

Nadine Mouton

NMRC Secretariat

World Patient Safety Day stands as a prominent global public health event orchestrated by the WHO.

World Patient Safety Day was established in May 2019 when the 72nd World Health Assembly adopted resolution WHA 72.6 on 'Global action on patient safety'. Its fundamental aims encompasses raising public awareness, fostering global understanding, and inspiring united action among Member States to strengthen patient safety measures and reduce harm to patients.

The central theme of World Patient Safety Day in 2022 was centred on "Medication Safety" encapsulated by the slogan, "Medication without Harm". The Ministry of Health and Social Services, in alignment with its mandate to ensure patient well-being, coordinated the observance of World Patient Safety Day 2022. The selected theme and slogan served as the catalyst for the Therapeutic Information and Pharmacovigilance Centre (TIPC), the national hub for monitoring medicine safety, to spearhead the outlined initiatives.

In a concerted effort to raise awareness about medication safety among stakeholders, a series of activities were undertaken during the week of 12 – 18 September 2022:

- **Live Panel Discussion**

A live discussion was hosted at the Government Information Centre on 15 September 2022,featuring several healthcare experts. This insightful discourse was broadcasted via social media, NBC1 television, and NBC radio stations. The panel, comprised of a medical doctor, nurse, and two pharmacists, sought to educate patients, caregivers, families, healthcare professionals, and the public about the roles played by various stakeholders in ensuring medication safety. The conversation spotlighted the collaborative endeavours necessary to achieve the objective of "Medication without Harm".

- **Dissemination of Campaign Materials**

The TIPC distributed posters and banners to hospitals, with over half of these materials finding their way to private hospitals, retail pharmacies, and doctors' practices in Windhoek. Additional posters were dispatched to state healthcare facilities across the country during a one-month period.

- **Windhoek Central Hospital Campaign**

Windhoek Central Hospital's pharmacy division, a healthcare institution in Namibia, collaborated with the TIPC to organise its own campaign on 16 September 2022. The hospital received support in the form of campaign materials, including banners and posters. The campaign effectively educated patients on the proper usage of medications, potential side effects associated with medicines, and the importance of reporting adverse events to the TIPC via designated pharmacovigilance forms. This initiative contributed to enhancing medication safety practices.

Live panel discussions are broadcast via social media and NBC1 television

World Patient Safety Day (WPSD) campaign at Windhoek Central Hospital

#MedSafetyWeek – November 2022

Frieda Shigwedha

NMRC Secretaria

#MedSafetyWeek Campaign: Enhancing Patient Safety through Awareness and Collaboration

#MedSafetyWeek is an annual initiative dedicated to promoting safe medication practices and raising awareness about medication safety. Hosted by the Uppsala Monitoring Centre in collaboration with the WHO, this campaign seeks to prevent medication errors, adverse drug events, and other issues associated with medication use. Namibia actively participates in this campaign, leveraging social media platforms to increase awareness and engagement.

Bringing Together Stakeholders for Safer Medication Practices

Namibia's participation in the 2022 #MedSafetyWeek Campaign involved collaboration with various stakeholders from the healthcare sector. Partnerships were established with entities such as the Ministry of Health and Social Services Public Relations Office, the University of Namibia, School of Pharmacy, and prominent media outlets including the Namibia Broadcasting Corporation (NBC) and the New Era newspaper.

The campaign had a dual purpose: encouraging the reporting of adverse drug events and educating communities on the significance of reporting adverse drug reactions. Communication efforts spanned diverse mediums such as the NBC national radio station, television programs like "Good Morning Namibia" and "The Daily Roundup with Nina," and an article published in the New Era newspaper. The campaign also led to the initiation of a WhatsApp broadcast to sensitise the public about the campaign.

Dr. Theo-Ben Kandetu (Deputy Executive Director - Ministry of Health) talking about #MedSafetyWeek on The Daily Roundup Show

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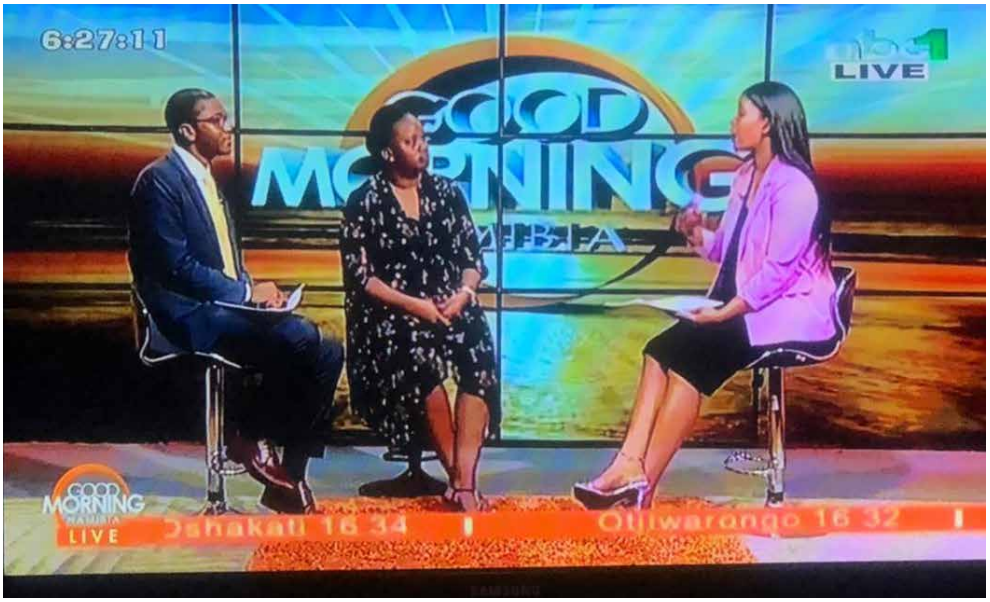
EMPOWERING PATIENTS AND HEALTHCARE PROFESSIONALS

#MedSafetyWeek underscores the importance of educating both patients and healthcare professionals. Through various resources, events, and educational materials, the campaign aims to spread awareness about potential risks associated with medication use. This includes proper medication administration, storage, dosage, and potential interactions. Patients are encouraged to actively engage with their healthcare providers, ask questions, understand treatment plans, and promptly report adverse effects.

Healthcare professionals, including doctors, nurses, and pharmacists, are encouraged to collaborate and enhance their knowledge of medication safety protocols. Open communication with patients is emphasised to ensure effective and safe medication practices.



Dr. Theo-Ben Kandetu (Deputy Executive Director - Ministry of Health and Social Services) and Ms. Frieda Shigwedha (Pharmacist – Therapeutic Information and Pharmacovigilance Centre) talking about #MedSafetyWeek on The Good Morning Namibia Show

Promoting Best Practices and Risk Reduction Strategies

The campaign highlights best practices for prescribing, dispensing, and administering medications. Strategies to mitigate medication errors within healthcare facilities are emphasised, including the incorporation of technology like e-prescribing and barcoding, clear labelling, accurate documentation, and standardised operating procedures.

Live panel discussion broadcasted via social media and NBC1 television; New Era newspaper article about #MedSafetyWeek

#MedSafetyWeek may advocate for policy changes on various levels, advocating for improvements in medication packaging, labelling, and patient education.

Engaging Activities for a Safer Healthcare Environment

A variety of engaging activities and events took place and involved a diverse audience throughout #MedSafetyWeek.

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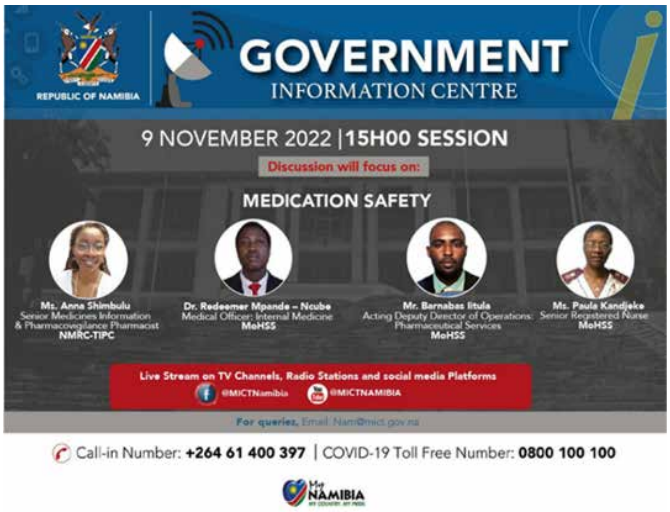
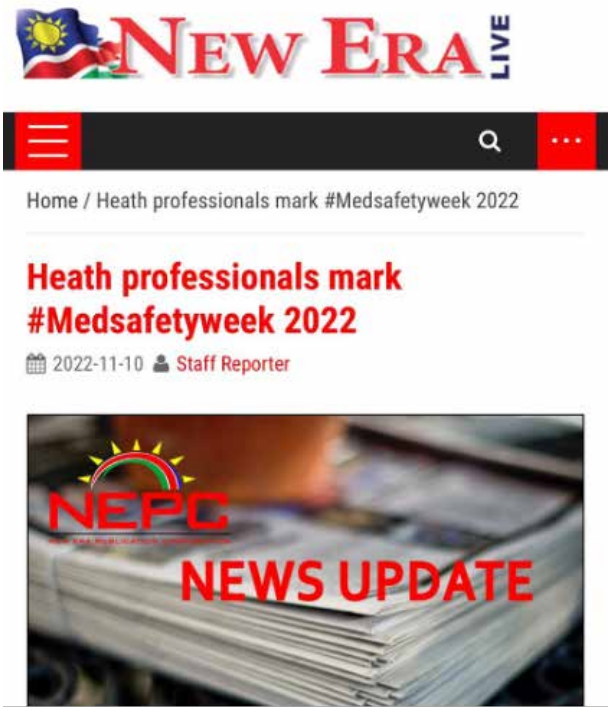
Enhancing Patient Safety and Healthcare Quality

#MedSafetyWeek plays a pivotal role in reducing medication errors and improving patient outcomes. By raising awareness, fostering collaboration among stakeholders, and promoting best practices, the initiative contributes to a safer healthcare environment. It empowers individuals to actively manage their medications, ultimately leading to enhanced patient safety and improved healthcare delivery.

In essence, #MedSafetyWeek stands as an annual beacon of safe medication practices. Through education, awareness, patient empowerment, and healthcare professional engagement, the campaign aims to prevent medication errors and adverse drug events, advancing patient safety and elevating the quality of healthcare delivery in the process. Namibia's active participation underscores its commitment to these ideals, building upon past successes to create a safer and more informed healthcare landscape.





Live panel discussion broadcasted via social media and NBC1 television; New Era newspaper article about #MedSafetyWeek

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Unveiling Insights:

Chelsea Moller

NMRC Secretariat

As outlined by the WHO, adverse events are the challenges that can arise when medications are taken as prescribed at standard doses. Adverse drug reactions (ADRs), in this context, are not tied to errors. [1] The practice of reporting these reactions, however, provides significant insights that enhance safety and expand our knowledge horizons.

- Uncovering Uncharted Territory: Reporting ADRs helps unveil lesser-known or unusual side effects of medications.
- Spotting Safety Signals: ADRs contribute to recognising potential safety signs or recurring patterns.
- Complementary to Clinical Trials: Clinical trials play a critical role in drug safety, although they may not capture all side effects due to their limited participant scope.
- Balancing Act: ADRs assist in evaluating whether the benefits of a medication are greater than its potential risks.
- Adverse drug reaction monitoring and reporting can be classified into active surveillance and passive surveillance. Active surveillance, as defined by the WHO, involves consistent, organised collection of case information. [2] This approach actively gathers safety data using predefined methods and sources aimed at uncovering potential adverse effects that might not be immediately apparent in spontaneous reporting systems. Passive surveillance, on the other hand, involves the collection and analysis of individual case reports from healthcare professionals. [3] These reports are submitted through adverse medicine reaction forms (commonly known as yellow forms) or the e-reporting tool.

In our analysis, we delved into the statistics related to adverse medicine reaction reports for the fiscal year 2022/2023. Nationally, we received and recorded 555 cases in Vigiflow. Among these reports, 315 did not specify age, while 7 indicated "adolescent," 159 indicated "adults," 6 indicated "child," 66 indicated "elderly," and 2 indicated "infant." Notably, females showed a higher reactivity to medications, accounting for 58.6% (325 cases), while male patients represented 35.1% (195 cases), with the remaining 2.5% (14 cases) falling into the unknown category.

Further analysis revealed that 74.9% (402 cases) were linked to systemic anti-infectives, while cardiovascular system cases accounted for 17.5% (94). Conversely, the least reported drug classes, such as blood and blood forming organs, systemic hormonal preparations (excluding sex hormones and insulins), antiparasitic products, insecticides and repellents, and unspecified categories, each contributed only 0.7% (4 cases).

Regarding active ingredients, Covid-19 vaccines took the lead at 45.3% (243 cases), followed by Perindopril at 9.3% (50 cases). The combination of Measles and Rubella at 6.5% (35 cases). Tenofovir Disoproxil accounted for 3.2% (17 cases), and the combination of Dolutegravir, Lamivudine, and Tenofovir disoproxil at 3.4% (18 cases).

Among the 555 cases, 36.9% (198 cases) were related to nervous system disorders, emerging as the most common reaction type. Subsequently, general disorders and administration site reactions stood at 36.7% (197 cases), gastrointestinal issues at 21.2% (114 cases), skin and subcutaneous disorders at 18.4% (99 cases), respiratory, thoracic and mediastinal disorders at 14% (75 cases), and musculoskeletal and connective tissue disorders at 12.5% (67 cases). Other reaction types were under the 10% mark, with ear and labyrinth disorders, hepatobiliary disorders, injury, poisoning, procedural complications, and neoplasms (benign, malignant, and unspecified, including cysts and polyps) were the least reported (each at 0.2% - 1 case).

In terms of specific reactions, headaches topped the list at 20.1% (108 cases), followed by dizziness at 15.6% (84 cases), and chills at 9.3% (50 cases). Pyrexia contributed to 8.6% (46 cases), vomiting to 8.4% (45 cases), coughing

Analysing Adverse Event Trends and Patterns in 2022-2023

to 8.2% (44 cases), and nausea, asthenia, and pain each at 7.3% (39), 6.7% (36), and 5.8% (31), respectively. Additionally, taste disorders, poor feeding in infants, and administration site swelling accounted for 0.2% (1 case) each.

Regarding the severity of cases, non-serious cases constituted 87.3% (469 cases), while 12.7% (86 cases) were categorised as serious. Among the serious cases, 5 were categorised as deaths, 17 were life-threatening, 35 led to prolonged hospitalisation, 6 resulted in disabling/ incapacitating conditions, and 23 were linked to other medically significant outcomes.

When examining reporter demographics, physicians contributed 19.7% (106 cases), pharmacists 5.8% (31 cases), and other health professionals 32.6% (175 cases). Consumer/non-health professionals accounted for 0.2% (1 case), and the rest were categorised as unknown. The analysis of adverse event statistics for 2022/2023 underscores the pivotal role of ADR reporting in pharmacovigilance. These insights elevate medication safety, patient care, and public health. By understanding the ins and outs of adverse reactions, healthcare professionals can make informed decisions about medication administration, attentive monitoring, and timely intervention.

Collaboration between healthcare professionals, patients, pharmaceutical companies, and regulatory entities ensures that the benefits of medications consistently outweigh their potential risks. This ongoing process of monitoring and analysing adverse events remains essential in advancing medication safety and advocating for patients on a global scale.

In essence, ADR reporting forms a cornerstone of pharmacovigilance – a collaborative endeavour involving scientific inquiry and actions aimed at detecting, understanding, evaluating, and preventing adverse effects and related concerns. Together, we ensure the safe and effective use of medications.

References

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REPORTING ADVERSE EVENTS

1. Adverse events following use of medicinal products other than vaccines are reported directly to the TIPC:

- ❑ **e-Reporting - https://primaryreporting.who-umc.org/NA**

(link also available on the website (https://nmrc.gov.na/tipc1)

You may also scan the following QR code with your mobile phone to report

1. Complete the Adverse Drug Reaction (Safety Yellow) form and send to:

- The pharmacy
- Email to info.TIPC@mhss.gov.na
- Fax2email: 088 660 6781
- Call TIPC @ 061 203 2468

2. Adverse Events Following Immunisation (vaccines) are first received by the Expanded Programme for Immunisation:

- Complete the AEFI reporting form
- Send form to Primary Healthcare Supervisors at the health facilities

  or email to AEFI@mhss.gov.na
- Call the national EPI focal person @ 081 669 1707

Pharmacovigilance activities – TB & HIV Active Surveillance

Nadine Mouton

NMRC Secretariat

In collaboration with the Directorate of Special Programs (DSP), the Therapeutic Information and Pharmacovigilance Centre (TIPC) established a National Technical Working Group (TWG) in 2019. The primary objective of this TWG is to streamline and oversee the vigilant monitoring of HIV and TB medicines employed within the program.

In September 2022, an implementation training program was conducted for ten healthcare facilities located in five different regions. The main objective of this program was to sensitise and empower healthcare workers to actively monitor the usage of newer HIV and TB medications in Namibia. The training program provided participants with essential tools, skills, and knowledge required to effectively implement active surveillance within their respective facilities. They were also trained to educate other healthcare workers within their regions.

The purpose of the active surveillance system currently being implemented in Namibia, is to collect local data that will be used to improve patient safety and treatment outcomes.

Specifically, the system will identify, record, and report any adverse reactions that may occur due to the use of new HIV and TB medicines during regular patient care. The data collected will be crucial in enhancing the effectiveness of treatments and ensuring the safety of patients.

To ensure effective support for active surveillance activities, the TWG conducted visits to the active surveillance sites. During these visits, the TWG evaluated the implementation progress and provided on-site training to healthcare workers involved in managing patients on the relevant medicines. The visits typically commenced with a gathering of medical professionals, nurses, pharmacy staff, and data clerks. These sessions included an introduction outlining the purpose of the visit and the on-site training activities.

It was discovered that there was a lack of adverse reaction data being reported at the national level regarding the management of HIV and TB. This lack of data meant that

Support Supervisory Visits and on-site training provided to the ten (10) active surveillance sites (healthcare facilities) in the regions

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Pharmacovigilance activities – TB & HIV Active Surveillance

many individuals were unaware of the ongoing active surveillance efforts. As a result, the TWG clarified its role as a national coordinating mechanism for medication safety and organised supervisory support visits and on-site training to ensure that active surveillance could continue to progress without any issues.

The TWG discussed the concepts of active and passive surveillance, focusing on the current project's active surveillance. They explained the reporting process in detail, from completing the reporting form to having data clerks enter the events into the system. They highlighted the importance of each stage of the reporting process, including the significance of accurately recording a "0" to indicate the absence of adverse events.

The TWG has recently clarified the eligibility criteria for active surveillance. This includes individuals who are transitioning to or initiating specific medications for HIV and TB. In particular, the TWG focused on the TB section and outlined the responsibilities of healthcare professionals in facilitating active surveillance. They emphasised the importance of regular blood tests and meticulous record-keeping of the conducted tests. The TWG also provided detailed explanations of the significance of each test and its implications. Additionally, they offered a comprehensive guide on completing the adverse reaction form and touched upon topics such as electronic reporting and safety yellow forms.

Finally, a focal person was designated from each healthcare facility to maintain communication with the TWG regarding active surveillance. The person was also responsible for raising awareness among staff members unaware of the program. The on-site training sessions were concluded with expressions of gratitude to all attendees and facilitators for their valuable contributions. The TWG expressed optimism for increased patient identification and participation in the active surveillance program, as well as a higher volume of adverse drug reaction reports.

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Pharmacovigilance Systems Strengthening Workshop – Strengthening Pharmacovigilance and Regulatory Capacities (SPaRCs) activities

Anna Shimbulu

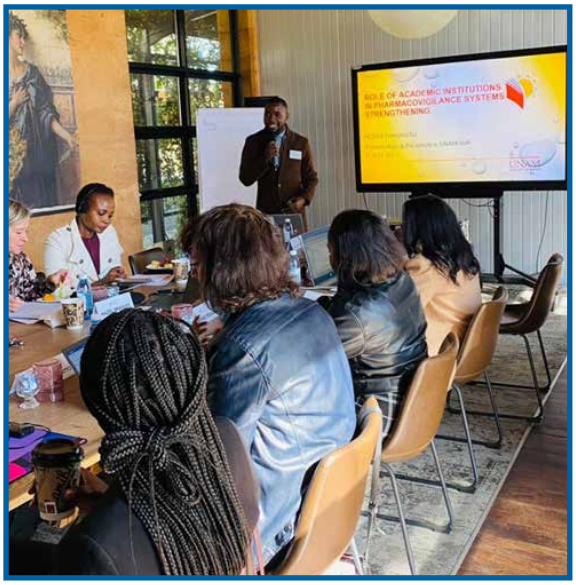
NMRC Secretariat

The Therapeutics Information and Pharmacovigilance Centre (TIPC) hosted the **Pharmacovigilance Systems Strengthening Workshop and Mutual Exchange Site Visits** from 10-14 July 2023 at Droombos Vineyard Country Lodge in Windhoek.

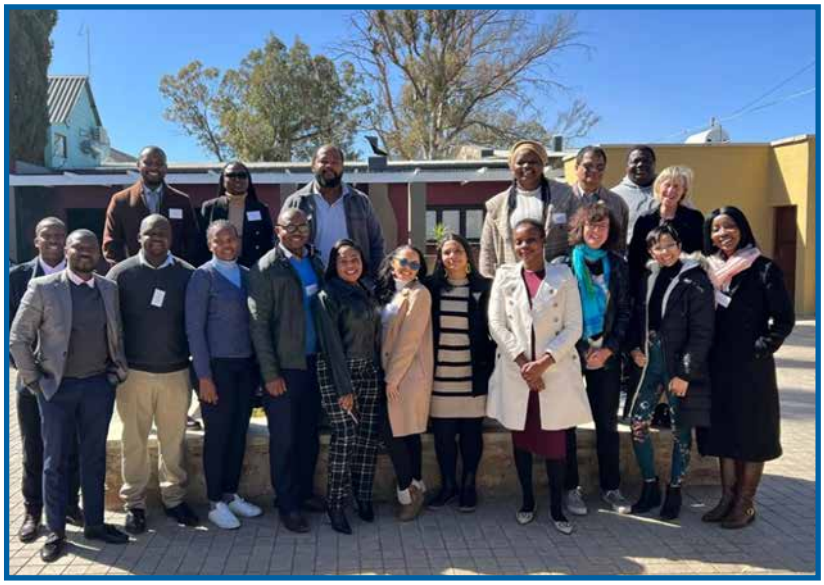
This workshop is a part of a three-year project funded by the European and Developing Countries Clinical Trials (EDCTP) aimed at strengthening pharmacovigilance systems and clinical trial oversight in four Southern African countries (Namibia, South Africa, Zimbabwe and Eswatini), called Strengthening Pharmacovigilance and Regulatory Capacities in four Southern African Countries (SPaRCs).

The SPaRCs project has partners from the University of Western Cape, national medicine regulatory authorities and Departments of Health of the participating countries. The technical experts from the Institute of Tropical Medicine, Belgium also participated in the project. The workshop was attended by additional participants from the regulatory authorities of Zambia and Mozambique who shared their experiences. Local speakers from the School of Pharmacy - University of Namibia and CDC Namibia also participated to provide insight into their roles in regulatory system strengthening.

The workshop was officiated by Mr. Johannes Gaeseb, Director of Tertiary Healthcare and Clinical Support Services on behalf of Ms. Petronella Masabane, Deputy Executive Director – Ministry of Health and Social Services.



Workshop session in progress by the speaker from the School of Pharmacy



SPaRCs workshop participants at Droombos Vineyard, Windhoek, Namibia

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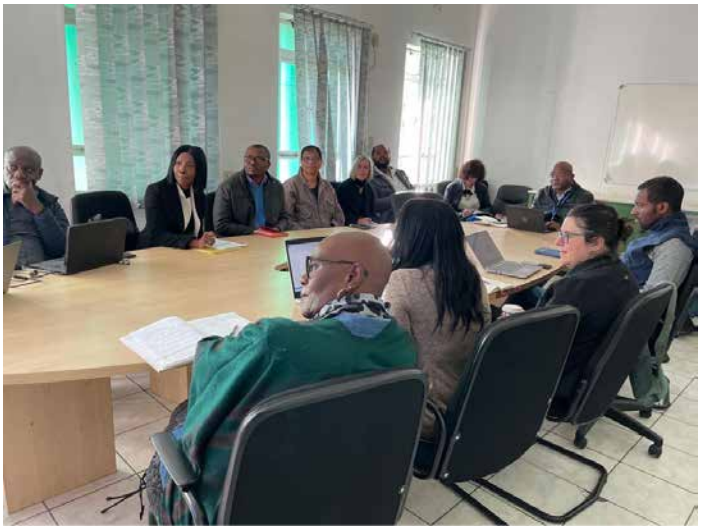
After the workshop, a representative from each partner country remained to participate in the site visits at the selected facilities, including meetings with the NMRC secretariat, Intermediate Hospital Katutura, GEKA Pharma, and attending the regular TB/HIV active drug safety monitoring technical working group (aDSM TWG) meeting. During the engagements, participants learned from the Namibian pharmacovigilance systems while also sharing good practices from their home countries.

Visit to the Intermediate Hospital Katutura, with the pharmacy team who have shared their pharmacovigilance systems

Visit to Geka Pharma, where the team shared initiatives to strengthen pharmacovigilance



Attending the TB/HIV aDSM TWG meeting at the Directorate of Special Programs

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AFRO Builds Capacity of 12 Member States to Improve Antimicrobial Resistance Surveillance

Dr Mary Brantuo (WHO Namibia)
Aina Erastus (WHO Namibia), Anastasia Aluvilu (WHO Namibia)

Windhoek Namibia, 20 October 2023

The World Health Organization (WHO) Regional Office for Africa (AFRO), WHO Headquarters in collaboration with WHO Namibia and the Ministry of Health and Social Services conducted a training session on Global Antimicrobial Resistance (AMR) and the utilisation of the surveillance system (GLASS) and WHONET tool in Windhoek for 12 selected member states. The training aimed to build the capacity of member states in improving national surveillance systems for AMR. The focus was on enabling them to generate, collect, report, and utilise quality data to inform decisions at the country, regional and global levels.

Addressing the commencement of the regional GLASS training, Dr. Mary Brantuo, Officer-in-Charge of WHO Namibia, underscored various initiatives spearheaded by WHO and partners to combat AMR. She highlighted the adoption of a Global Action Plan on AMR by the World Health Assembly in 2025, and the subsequent launch of the GLASS later that same year to standardise AMR surveillance. Dr. Brantuo noted that approximately 80% of member states in the WHO African Region, including Namibia, have registered for GLASS. Globally, 130 member states have registered for GLASS.

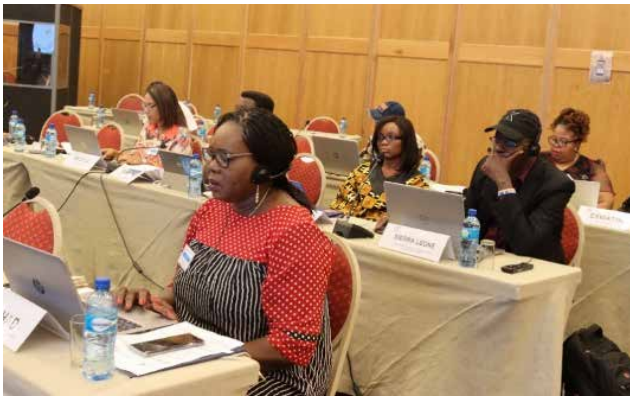
Antimicrobial resistance (AMR) poses a serious threat to the effective prevention and treatment of an ever-increasing range of infections caused by bacteria, parasites, viruses, and fungi. This issue is rapidly emerging as a global public health concern and currently ranks among the top ten global threats to public health. In 2019 alone, 4.95 million deaths were attributed to drug-resistant bacterial infections, with the sub-Saharan Africa Region bearing the most substantial burden, accounting for 1.07 million deaths due to bacterial resistance . The most recent 5th GLASS report (December 2022) highlights a global increase in AMR-related cases involving pathogens causing bloodstream infections (such as Klebsiella pneumoniae and Acinetobacter spp.), showing a growth of more than 15% in 2020. This underscores the need for concerted efforts to strengthen infection prevention and control measures in hospital settings.

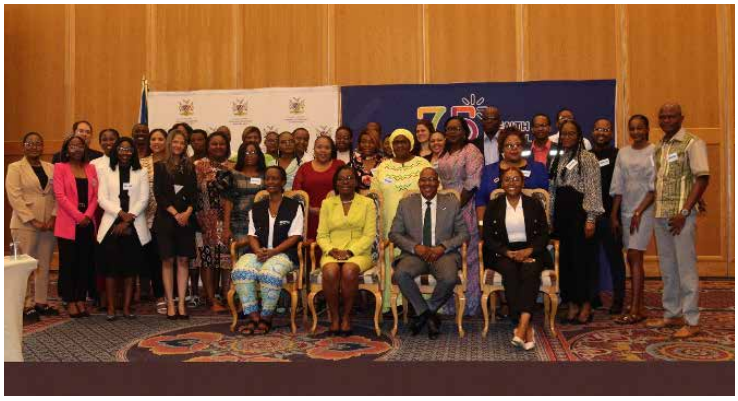
Dr. Brantuo highlighted the challenges many countries face in the realm of AMR surveillance capabilities and laboratory infrastructures. She emphasised the need for capacity development to generate, collect, report, and use high-quality AMR data, adhering to GLASS guidelines and utilising the WHONET tool - a free desktop Windows application developed by a WHO Collaborating Centre for the management and analysis of microbiology laboratory data, with a specific focus on antimicrobial resistance surveillance.

Speaking at the same occasion, Mr. Ben Nangombe, Executive Director of the Ministry of Health Social Services said that the meeting represents more than a convergence of minds and expertise; it serves as a testament to the *'unwavering commitment of our nations to address one of the most pressing global health challenges: the rise of antimicrobial resistance (AMR)'. He further said that 'in an age where borders blur, diseases know no boundaries, and pathogens evolve at an alarming rate, collaboration and shared knowledge are our most potent weapons. Africa remains the continent most afflicted by infectious diseases and AMR can dramatically hamper treatment effectiveness and greatly amplify disease burden and its complications'.*

He accentuated the threat posed by AMR that as societies advance so *'too do the microbial adversaries we face'.* Mr. Nangombe stated that *'infections that were once treatable now pose life-threatening challenges. The emergence of drug-resistant pathogens knows no discrimination, impacting not only human health but also animal health, agriculture, and the environment. If we do not act decisively, we risk sliding into a future where common infections become fatal, medical procedures become perilous, and healthcare systems strained under the burden of untreatable diseases'.*

The Namibia meeting had representation from 12 WHO Africa Region member states: Angola, Benin, Burundi, Cabo Verde, Chad, Eswatini, Gabon, The Gambia, Liberia, Namibia, Senegal, Sierra Leone.





Pictures from the GLASS 2.0 and WHONET tool training session held at Mercure Hotel, Windhoek from 17-20 October 2023

Quality Surveillance Laboratory (QSL) - Tests Performed Under Scope of Accreditation

Samuel Shuuya
NMRC Secretariat

The Quality Surveillance Laboratory (QSL) serves as the testing arm of the NMRC, a statutory body established under the Medicines and Related Substances Control Act, (Act No. 13 of 2003), to oversee the regulation of medicines in Namibia. Accredited by the Southern African Development Community Accreditation Service (SADCAS) with accreditation number: TEST-5 0071, the QSL adhered to the internationally recognised standard ISO/IEC 17025:2017.

Within its current scope of accreditation, the QSL conducts various tests, including Identification, Assay, Dissolution, Disintegration, Uniformity of Weight and Uniformity of Content. This accreditation underscores the laboratory's commitment to maintaining high testing standards in the field of medicines and related substances.

* **The pharmaceutical** identification test is based on the composition, structure and properties of pharmaceuticals using either chemical, physical and/or biochemical methods in order to ascertain the authenticity of a particular pharmaceutical product. At QSL, several techniques are utilised

to confirm the identity of a pharmaceutical product. These include High-Performance Liquid Chromatography (HLPC), Ultraviolet Visible light Spectroscopy (UV-Vis), Fourier-transform infrared spectroscopy (FT-IR), Thin layer chromatography (TLC) and Chemical identification methods, including colour reaction identification, and precipitation formation reactions.

- **An assay** is an analytical procedure for assessing the presence and amount of a pharmaceutical product. Manufacturers of pharmaceutical products must adhere to stringent regulatory guidelines, substantiating that their products are of high quality, safe, effective, and free of contamination and defects. Assays play an important role by determining the concentration of a drug compared to its labelled amount. QSL performs assay tests on finished pharmaceutical products by using techniques such as High-Performance Liquid Chromatography (HLPC), Titration, and Ultraviolet Visible Light Spectroscopy (UV-Vis).
- **Dissolution** is the process in which a substance forms a solution. A dissolution test is used to measure the extent and rate of solution formation from a dosage form, such as tablet, capsule, etc. The dissolution of a drug is important for its bioavailability and therapeutic effectiveness because dosage forms such as tablets and capsules rely on the drug dissolving in the gastrointestinal tract before absorption into the systemic circulation. Determining the rate of dissolution of a drug is therefore imperative for assessing its efficacy. QSL performs dissolution tests on finished pharmaceutical products by using two techniques; High-Performance Liquid Chromatography (HLPC) and Ultraviolet Visible Light Spectroscopy (UV-Vis).
- **Disintegration** refers to the mechanical break up of a compressed tablet into small granules upon ingestion. It is characterised by the breakdown of the inter-particulate bonds, which are forged during the compaction of the tablet. In this process, a solid dosage form breaks down into smaller particles or fragments when exposed to fluids in the gastrointestinal tract. Disintegration is a necessary step for dissolution to occur, as the smaller particles created by disintegration have a greater surface area and can dissolve more rapidly. Disintegration testing is used to determine the time required for a solid dosage form to disintegrate into its constituent particles under standardised conditions.
- **Uniformity of Weight** is conducted on tablets and capsules to ensure the precise and consistent dosage that patients will administer. The procedure involves individually weighing 20 units selected randomly and then calculating the average weight. This meticulous testing process ensures that each tablet or capsule within a batch meets the specified weight criteria, thereby contributing to the uniformity and accuracy of the dosage form.
- **Uniformity** of Content is a critical pharmaceutical analysis parameter utilised for the quality control of capsules or tablets. This involves the random selection of multiple capsules or tablets, and a suitable analytical method is applied to assay the individual content of the active ingredient in each capsule or tablet. QSL performs uniformity of content tests on finished pharmaceutical products by using two approaches: Content Uniformity (CU) or Weight Variation (WV). These methodologies ensure that each unit within a batch contains the specified amount of active ingredients, contributing to the overall quality and consistency of the pharmaceutical product.

Note: * represents unaccredited technique.

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