



Medicines Control Authority of Zimbabwe



Annual Report 2023



Medicines Control Authority of Zimbabwe

**Protecting Your Right to Quality
Medicines and Medical Devices**

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Abbreviations list

1. AEFI - Adverse Events Following Immunization
2. AER - Adverse Event Reporting
3. AFENET - African Field Epidemiology Network
4. ARV - Antiretroviral
5. CBD - Cannabidiol
6. CDC - Centers for Disease Control and Prevention
7. DRC - Democratic Republic of Congo
8. DSMB - Data Safety Monitoring Board
9. EVR - Evaluations and Registrations Division
10. GBT - Global Benchmarking Tool
11. GCP - Good Clinical Practice
12. GF/UNDP - Global Fund/United Nations Development Programme
13. GMP - Good Manufacturing Practices
14. HIV - Human Immunodeficiency Virus
15. ICSR - Individual Case Safety Reports
16. ICT - Information and Communication Technology
17. LMIC - Low and Middle-Income Countries
18. MAH - Marketing Authorization Holders
19. MoU - Memorandum of Understanding
20. NDS1 - National Development Strategy 1
21. NRA - National Regulatory Authorities
22. PVCT - Pharmacovigilance and Clinical Trials Division
23. QPPV - Qualified Person for Pharmacovigilance
24. SADCAS - Southern African Development Community Accreditation Service
25. SMS - Short Message Service
26. SPaRCS - Strengthening Pharmacovigilance and Regulatory Capacities in Southern Africa
27. TEN - Toxic Epidermal Necrolysis
28. TMPCZ - Traditional Medicines Practitioners Council of Zimbabwe
29. UNDP - United Nations Development Programme
30. USA - United States of America
31. VigiFlow - WHO's Global Individual Case Safety Report (ICSR) Database System
32. WHO - World Health Organization
33. ZIMDIS - Zimbabwe Drug Information System

▶ Chairperson's Statement

Introduction

On behalf of the MCAZ Board, I am pleased to present to our stakeholders the business performance for the financial year ending 31st December 2023. Our operations continue to be guided by the Medicines and Allied Substances Control Act (Chapter 15:03) and the accompanying regulations, as well as the administration of the Dangerous Drugs Act.

MCAZ's strategy is anchored on the National Development Strategy 1 (NDS1) and the National Pharmaceutical Policy. I am pleased to report that the Authority has successfully facilitated the provision of safe, quality, and effective medicines, achieving its set goals and executing its mandate.

Overall Performance

The operating environment for the period under review was challenging due to inflationary pressures and unstable exchange rates. Rising inflation exerted pressure on the Authority's finances. Detailed financial performance is attached to this report. With the Government's ongoing efforts to stabilize the operating environment, MCAZ is poised to enhance its efforts towards protecting public and animal health. Despite these

challenges, I am glad to report that the Authority met most of its set goals and objectives for the year. I urge management and staff to continue working hard, utilizing the available resources to ensure public safety.

Governance/Directorate

The Authority complied with the requisite legislative and corporate governance requirements throughout the accounting period under review. In 2023, the Board held four quarterly meetings and made decisions on all issues brought to its attention.

The Board comprised ten non-executive directors with a diverse range of skills, expertise, and experiences, enabling informed decision-making, effective governance, and fostering a culture of collaboration and innovation. Dr. V.L.

Makanza, a Specialist Physician, joined the Board in August 2023, bringing a wealth of experience.

In January 2023, Mr. Richard T. Rukwata was confirmed as the substantive Director-

I am pleased to report that the Authority has successfully facilitated the provision of safe, quality, and effective medicines, achieving its set goals and executing its mandate.



General. We wish Mr. Rukwata well as he continues to lead the MCAZ management team and staff. To improve compliance with the corporate governance framework, the Board assigned the Legal Manager the duties of a company secretary.

Strategy


The Board continued its oversight role in implementing the Authority's strategic plan through various Board Committees. The year 2023 marked the second year of the 5-year strategic plan (2022-2026), guided by the National Development Strategy (NDS1) and the National Pharmaceutical Strategy (2021-2025). This National Pharmaceutical Strategy aims to improve local drug production, increase the availability of essential medicines, and position Zimbabwe as a net exporter of medicinal consumables. Our Good Manufacturing Practices (GMP) inspectors ensure local pharmaceutical manufacturers comply with GMP, producing products under internationally recognized standards.

In line with our strategic goal to attain Global Benchmarking Tool (GBT) Maturity Level 3 (ML3),

MCAZ was assessed by the World Health Organisation (WHO) in May 2023. Several improvement and development plans (IDPs) were identified, and management and staff have worked diligently to address them. Subsequent meetings were held virtually, and significant progress has been made towards attaining GBT ML3.

Appreciation

I extend my deepest appreciation to the Ministry of Health and Child Care for their support. I also thank our various stakeholders, strategic partners, and customers for their continued support. I commend the Board, Management, and staff of MCAZ for their unwavering commitment and dedication despite the challenging operating environment. I hope you will all continue your commitment as we work towards delivering on our mandate of protecting public and animal health by ensuring that all medicines available in the Zimbabwean market are safe, efficacious, and of good quality.



Dr. Misheck Chiware
Authority Chairperson



▶ Director-General Statement

It is my pleasure to present you the 2023 Annual Report. As we reflect on the period under review, which encompasses the year 2023, I would like to take this opportunity to highlight both the challenges and successes that the Authority has encountered. Despite the challenging global and domestic macroeconomic environment, the local pharmaceutical industry experienced growth as this report will reveal. The regulatory framework remained robust ensuring that the right of citizens and animals to safe, good quality, and efficacious medicines and medical devices is protected.

Business Process

Licenses: The Authority witnessed an increase in the licensure of pharmacies from one thousand one hundred and forty-six (1146) in 2022 to one thousand two hundred and twenty-seven (1227) in 2023. Two (2) new manufacturers were licensed in 2023, bringing the total cumulative for manufacturers to eighteen (18). 2023 however witnessed a decline in licences issued for dispensing medical practitioners.

Enforcement: There was a notable increase in inspections of licensed premises from 2022 to 2023. The impact of Covid-19 on the Authority's operations in 2022 likely influenced this trend. The need for post-marketing sampling and surveillance led to inspections of one hundred and fifty-eight (158) public institutions. Seven hearings were conducted for those found to contravene the law.

Registration: The Authority recorded a 29% increase in new applications for registration of allopathic human medicines in 2023. The statistics reveal that 350 new applications for human allopathic medicines were received in 2022 against 452 new applications for human allopathic medicines that were received in 2023. There has been a steady growth in registration applications (approximately 100%) from the years 2020 to 2023. The Veterinary unit recorded a 253% increase in applications received from the previous year. In line with the government's thrust to recognize traditional medicines as an accepted means of treating and curing illnesses in Zimbabwe, the Authority aims to incorporate the regulation of traditional medicines within the scope of complementary medicines. This initiative also involves the development of Good Manufacturing



Practice (GMP) guidelines and regulations that align with local practices and traditions.

Automation: The Authority’s strategic goal is to fully automate all its operations by 2026. In this regard, the Authority developed a new Zimbabwe Drug Information System (ZIMDIS). The system was developed internally with the MCAZ developers. The system will be used for medicines evaluation and registration processes. Successful deployment of the AEFI VigiMobile and VigiFlow for AEFI reporting apps which led to an increase in the number of Adverse Event Following Immunisation (AEFI) reports received and improved reporting timelines.

Human Capital: The Authority values its people and appreciates their contribution towards the success of its business. Our skilled staff continue to be on demand both locally and abroad and this resulted in staff attrition being a challenge. The year 2023 marked improvement in the Authority’s continual efforts towards employee engagement as the engagement index increased from 49% to 52%. Significant reduction of the vacancy rate from 12% to 7% with key positions filled. The introduction of new monetary and non-monetary benefits such as mortgage scheme, motor vehicle loan scheme, and personal loan scheme has managed to improve the Authority’s staff retention.

Cannabis: The Licensing and Enforcement – Cannabis Desk was formed in 2018 to administer the S.I. 62 of 2018 on behalf of the Ministry of Health and Child Care. This encompasses matters on new applications for site licences, applications for renewal, variation or amendment of licences for sites or persons, the production, handling, import, and exportation of controlled substances, and all compliance issues relating to controlled substances.

With the successful completion of the Cannabis laboratory setup, testing commenced in 2023. Samples submitted for analysis were in different forms such as flowers (41%), oils (32%), powders (18%), semi-solid (5%), and biomass (4%). More samples are expected to be tested in the coming years owing to more equipment being installed and calibrated.

In 2023, Zimbabwe recorded its first commercial export of medicinal Cannabis. The dried

cannabis flower was exported to Europe.

Customer Satisfaction Survey: The Authority is committed to the delivery of quality service. As part of the continuous improvement process, a client satisfaction survey was commissioned through an independent research agency. The overall satisfaction index recorded in 2023 was at 71%. These results helped to reaffirm our commitment to the delivery of quality service to our stakeholders.

Legal Framework: The Authority needs enabling legislation to fulfill its mandate. The Authority has finalized and submitted draft regulations to the Minister of Health and Child Care. The Ministry also approved the concept note, that was submitted by the Authority on the proposed amendments to the Medicines and Allied Substances Control Act (Chapter 15:03) and further approved the request by MCAZ to consult stakeholders on the proposed amendments. As the regulator, we will continue to engage the parent ministry to expedite the approval of the pending legislation.

Collaborations: The Authority signed some strategic Memorandum of Understanding with other national medicines regulatory authorities (nMRA) such as the Egyptian Drug Authority (EDA), and the South African Health Products Regulatory Authority (SAHPRA). The collaborations are a reflection of the Authority’s commitment to safeguarding public health and ensuring the efficacy, safety, and quality of medical products available in the Zimbabwean market.

The Global Benchmarking Tool Maturity Level 3 (GBT ML3)

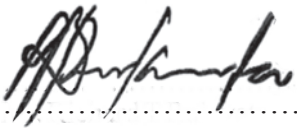
Currently, the Authority is pursuing the attainment of WHO GBT Maturity Level 3. GBT ML3 which speaks of a stable and well-functioning regulatory system. GBT represents the primary means by which WHO objectively evaluates regulatory systems, enabling WHO and regulatory authorities like MCAZ to identify strengths and areas of improvement. The Authority was assessed in May 2023. Although some functions such as Vigilance and Clinical Trials managed to achieve ML3, the overall for the organization was

The Microbiology Laboratory is working towards attaining WHO Prequalification Status, which will further enhance the reliability of laboratory test results and gain international recognition.

Maturity level 2. The Authority implemented the identified institutional development plan as recommended by the assessors. Subsequent meetings were held virtually throughout the year. Another assessment is scheduled for May 2024 and I believe we will achieve our target of ML3.

The Future

The Authority hopes to achieve the GBT ML3 in 2024. The Authority plans to volunteer in the pilot Veterinary Global Benchmarking Tool (VGBT) self-assessment being implemented by the United Kingdom Veterinary Medicines Directorate (UKVMD) and the World Organisation for Animal Health. The Authority through the Chemistry division is expanding the scope of testing to include DEG/EG in liquid/oral preparations, cannabis-formulated products, and complementary medicines using new equipment available in our laboratories. The Microbiology Laboratory is working towards attaining WHO Prequalification Status, which will further enhance the reliability of laboratory test results and gain international recognition. Going forward, the Authority envisages being an attractive employer of choice by implementing various sustainable programmes and projects that include talent management inclusive of career growth and succession planning, entrenched value-based culture programmes, and comparable remuneration structures among others.



Mr. Richard T Rukwata
Director – General

▶ Governance & Risk Report

Introduction

Effective corporate governance is a crucial element in the success and sustainability of the Authority as it ensures accountability, transparency, and responsible decision-making. Good governance practices promote a culture of integrity, mitigate risks, and foster trust among the Authority's stakeholders, employees, customers, and the wider community. By establishing clear roles, responsibilities, and oversight mechanisms, corporate governance enables the Authority to optimize performance, manage resources efficiently, and serve the public interest with integrity and accountability. As the Authority performs its regulatory mandate, the importance of robust corporate governance cannot be overstated.

To ensure improved compliance with the corporate governance framework, in 2023, the Board assigned the Legal Manager to perform

the duties of a Company Secretary. The Board also set up a Risk Management Committee and Integrity Committee in line with Corporate Governance requirements.

Role of the Board

The role of the Board is to provide leadership, guidance, and oversight to ensure that the Authority is operating in an effective, efficient, and responsible manner. The Board is also responsible for setting the strategic direction and goals of the Authority, managing risk and ensuring internal controls are in place and ensuring transparency and accountability in governance and the operations of the Authority.

In 2023, the Board held four (4) quarterly meetings and made decisions on all issues that were brought to its attention.

Annual General Meeting

The Annual General Meeting was held on the 8th of September 2023. The Annual General Meeting provided a platform for the Authority to disclose to the stakeholders information about the Authority's operations, strategy and financial position. The Annual General Meeting also offered stakeholders an opportunity to give feedback to the Authority.

Board Composition

The Board comprised of ten (10) non-executive directors with a wide range of skills, expertise, and experiences. This diverse mix of skills and perspectives enabled the Board to make informed decisions, drive effective governance, and foster a culture of collaboration and innovation. Dr. V.L. Makanza, a Specialist Physician, joined the Board in August 2023 and brings a wealth of experience to the Board.



Board Committees

The Authority's Board Committees were established to assist the Board in discharging its mandate effectively. The Committees carry out specific tasks and responsibilities delegated by the Board. They provide expertise and specialized knowledge to the Board. The Committees make recommendations to the Board through reports brought before the Board by the respective Committee Chairpersons who are also Board members.

In 2023, there were sixteen (16) Board Committees. Below is a list of the Committees, including the attendance record for each of the members for the period January to December 2023. Information on the attendance record of Board Members has also been included.

	COMMITTEE	MEMBERS	MEETINGS ATTENDED/HELD	RESPONSIBILITIES
1	Authority	Dr. M. Chiware Dr. C. Duri Dr. S.L. Mutambu Dr. S.C. Mutisi Mr. P. Mwendera Mrs. N. Samuriwo Mr. D.N. Vuragu Dr. E.O. Waniwa Air Cdre. P.G.S. Zimondi Dr. V.L.Makanza	4/4 4/4 4/4 4/4 4/4 3/4 4/4 4/4 4/4 2/2	Determines the Authority's purpose and values, sets the strategy to achieve the purpose of the Authority and exercises leadership, enterprise and integrity for the Authority to attain its objectives. The Board also ensures establishment of systems to protect the assets and the reputation of the Authority, approves, monitors and evaluates the implementation of strategies, policies and business plans and identifies key risk areas in order to generate stakeholder confidence.
2	Registration	Dr. C. Duri Dr. E.O. Waniwa Dr. C. Pasi Dr. R. Chigwanda Mr. E. Mupanehari Dr. D. Tagwireyi Dr. V. Makanza Mr. B. Chikati Dr. M. Murwira	12/12 9/12 8/12 12/12 8/12 11/12 3/3 2/2 4/4	Oversight and statutory decision making on registration of medicines

3	Laboratory	Dr. S.L. Mutambu Dr. E.O. Waniwa Prof. M. Gundidza Mr. N. Madzikwa Mrs. N.T. Mandizha Mr. B. Chikati	4/4 4/4 4/4 3/4 4/4 1/1	Gives guidance with respect to current quality standards for the laboratories and assist in the attainment and maintenance of such standards as required. Also focuses on the quality control testing of medicines and medical devices.
4	PVCT	Dr. C. Duri Dr. E.O. Waniwa Dr. C. Pasi Mrs. J. Chaibva Dr. I. Phiri Dr. C.E. Ndlovu Dr. A. Mushavi Mr. N. Madzikwa Ms. S. Ruzariro Dr. D. Tgwireyi Dr. R. Nyikadzino Mrs. R. Chapereka Dr. V. Makanza Dr. T. Mazhindu	12/12 9/12 7/12 4/4 8/12 5/9 8/12 6/12 10/12 9/12 12/12 2/2 2/2 1/1	Pharmacovigilance of medicines, medical devices and vaccines including COVID-19 vaccines, AEFI surveillance. Clinical trials regulation and oversight, clinical trial protocol applications evaluations, monitoring of clinical trials, GCP inspections, amendments & safety reports. Review of safety of medicines, safety variations, change of category for distribution and/or indications. Review of promotional material of medicines. Post-registration safety variations and post-marketing surveillance.
5	Veterinary	Dr. E.O. Waniwa Dr. S.L.Mutambu Mrs. J. Chaibva Dr. C.T. Hodobo Dr. Ndengu Dr. P.S.A. Woods Dr. F.T. Makuvadze Dr. V.L. Makanza	5/6 5/6 2/2 5/6 6/6 6/6 5/6 1/1	Oversight and statutory decision-making on registration of veterinary medicines.

6	Licensing and Advertising	Dr. M. Chiware	10/11	Makes decisions on the outcome of inspection for new premises applications, routine inspections, advertising material and enforcement activities. Also decides on whether or not to issue a license/permit for premises and persons handling medicines.
		Air Cdre. P.G.S. Zimondi	11/11	
		Dr. A.F. Zinanga	4/4	
		Mrs. M. Mothobi	11/11	
		Ms. R.C. Makunike	11/11	
		Mr. N. Madzikwa	8/11	
		Dr. C. Nyatsambo	2/2	
7	Audit	Dr. C. S. Mutisi	4/4	Assists the Board in reviewing and monitoring the performance of internal controls, risk management, governance systems and the integrity of the Authority's financial statements and its financial reporting system.
		Air Cdre. P.G.S. Zimondi	4/4	
		Mr. C.D. Mahofa	4/4	
		Miss N.G. Maphosa	4/4	
		Mrs. D.K. Shinya	2/4	
8	Human Resources	Air Cdre. P.G.S. Zimondi	4/4	Provides leadership and guidance in, and have control over all Human Resources affairs of the Authority through policies, systems and procedures designed to ensure that the Authority achieves its objectives.
		Dr. C. Duri	4/4	
		Mr. E. Jinda	1/4	
		Mr. C. Chiketa	4/4	
		Mrs. F. Chinongurei	4/4	
		Mrs. J. Ncube	1/1	
9	Finance	Dr. C. Duri	4/4	Planning for the Authority's financial position and financial control systems. Also ensures that the Authority discharges its financial responsibilities correctly and that it remains financially viable at all times.
		Dr. M. Chiware	3/4	
		Mr. I. Ruzengwe	3/4	
		Mr. C. Shoniwa	1/4	
		Dr. A.Z. Zinanga	1/1	
		Mrs. C. Chiguvare	1/1	

10	Legal	Mrs. N. Samuriwo Mr. P. Mwendera Mrs. J. Ncube Mrs. J. Chaibva Mr. D. Moyo Ms. S. Mutangadura	5/6 6/6 2/2 2/2 6/6 2/2	Providing guidance on all legal issues pertaining to the Authority, reviewing and drafting legislation and policies.
11	Legal Drafting	Dr. C.S. Mutisi Mrs. J. Chaibva Ms. N. Munjoma	1/1 1/1 1/1	Reviews legislation
12	Complimentary Medicines	Mr. P. Mwendera Mr. D. N. Vuragu Dr. D. Tagwirei Prof. L.S. Chagonda Mr. D.T. Chagwena Dr. T.R. Muzamhindo Mr. O. Ndoro	5/6 4/6 6/6 6/6 1/6 5/6 5/6	Oversight and statutory decision-making on registration of Complementary medicines.
13	Controlled Substances	Air Cdre. P.G.S. Zimondi Dr. C.S. Mutisi Mr. N. Madzikwa Mr. O. Madhume Mr. M.L. Musiyambiri Mr. D. Matondo Dr. A.M. Dube Ms. F. Ndhlovu Mr. P.F. Takaza Mr. D.T. Savadye Dr. D. Kutywayo Ms. R. Mudarikwa	4/4 3/3 3/4 4/4 4/4 3/4 4/4 4/4 4/4 3/4 4/4 4/4	To oversee all controlled substances issues of the Authority's functions. This encompasses matters pertaining to new applications for licences for sites, applications for renewal, variation or amendment of licences for sites, the production, handling, import, and exportation of controlled substances and all compliance issues relating to controlled substances.

14	Hearing	Mr. D.N. Vuragu	7/7	Conducts hearings into matters referred to it from the Licensing and Advertising Committee and make appropriate decisions for and on behalf of the Authority.
		Mrs. N. Samuriwo	3/7	
		Mr. D. Moyo	7/7	
		Mrs. J. Ncube	2/2	
15	Percentage Discount	Dr. E.O. Waniwa	4/4	Percentage Discount Company is a subsidiary of the Authority. The Members ensure the establishment of systems to monitor and safeguard assets of the company.
		Mr. D.N. Vuragu	4/4	
		Dr. P. Muvavarirwa	4/4	
16	ICT	Mr. P. Mwendera	6/6	Considers all ICT projects brought before it from all Units considering the project cost and its return on investment to the Authority. The Committee recommends the prioritized list of projects reflecting the merits of the projects.
		Air Cdre. P.G.S. Zimondi	6/6	
		Ms. C. Chanaiwa	4/6	
		Mr. M. Chikonye	4/6	
		Mr. G. Kabungaidze	5/6	

Management

The Director-General is the chief visionary, and strategic leader of the Authority and is responsible for setting the Authority's overall direction and vision. The Director-General is supported by Management which plays a crucial role in driving the success of the Authority by translating strategy into action, leading by example, and empowering teams to achieve results.

In January 2023, the Acting Director-General, Mr Richard Rukwata, was confirmed as the substantive Director-General. We wish Mr Rukwata well as he continues to steer the ship.

In the same year, three Managers resigned, that is, Mr. C. Shamuyarira (former Head of Chemistry), Mrs. R. Gwata (former Finance Manager), and Mr. T.A. Vambe (former Procurement and Administration Manager). The Authority would like to thank these members for their immense contributions during their tenure and wish them well in their new endeavours.

The Authority welcomed back Ms. A. Verenga who had left the Authority in 2022 and rejoined the Authority as a Chief Regulatory Officer in the

Licensing and Enforcement Division. The Authority also welcomed Ms. S. Msimanga who joined the Authority as an Internal Auditor. Below is the 2023 MCAZ Management team.



	Name	Position
1.	Mr. R. Rukwata	Director-General
2.	Mr. F.B. Masekela	Head Evaluations and Registrations
3.	Mrs. P.P Nyambayo	Head Pharmacovigilance and Clinical Trials
4.	Mr. K. Dzawo	Head Chemistry
5.	Mrs. C.G. Samatanga	Head Licencing and Enforcement
6.	Ms. R.B. Tugwete	Head Finance
7.	Dr. T. Munhenga	Head Human Resources
8.	Mr. T. Gonho	Microbiology and Medical Devices Manager
9.	Mrs. A. Chikowore	Quality Manager
10.	Mrs. R.P. Chimhenga	Legal Manager
11.	Ms. S. Msimanga	Internal Auditor
12.	Mr. T.E. Mukanga	ICT Manager
13.	Mr. A. Nyathi	Procurement and Administration Manager
14.	Ms. T. Muvirimi	Chief Regulatory Officer-EVR
15.	Dr. Z.A. Makoni	Chief Regulatory Officer-EVR
16.	Mr. L. Chirinda	Chief Regulatory Officer-PVCT
17.	Ms. A. Verenga	Chief Regulatory Officer-LED
18.	Ms. S. Shambira	Chief Regulatory Officer-LED
19.	Ms. N. Seve	Chief Analyst-Chemistry

Internal Controls

The Authority recognizes the critical role of internal controls in maintaining the highest standards of governance and accountability within its operations. Our internal controls framework serves as a fundamental pillar in ensuring the integrity, efficiency and effectiveness of our operations. Our internal controls framework is designed to safeguard the regulatory processes and promote transparency, accountability, and compliance within the organization. By implementing a comprehensive system of checks and balances, we strive to minimize the risk of errors, fraud, and regulatory non-compliance.

Our internal controls encompass various aspects of our operations, including the evaluation and registration of medicines, licensing of pharmaceutical companies, and monitoring of post-market activities. We have established clear policies, procedures, and guidelines to govern these processes, ensuring consistency, fairness,

and adherence to regulatory standards.

To enhance the effectiveness of our internal controls, we have an independent Internal Audit function and Audit Committee. Internal Audit conducts regular reviews and assessments of the Authority's control environment to identify potential weaknesses, evaluate compliance with established procedures and recommend improvements. The findings and recommendations of internal audits are promptly addressed and corrective actions are implemented to strengthen our control framework.

The Audit Committee, comprised of independent experts with relevant expertise, oversees the internal control and risk management processes of the Authority. The committee acts as an independent and objective body, providing oversight and guidance on matters related to internal controls, financial reporting

“The committee’s insights and recommendations will enable us to proactively address emerging risks, enhance regulatory compliance, and safeguard public health.”

and compliance. They review the effectiveness of our internal control systems, including the Internal Audit function, and ensure that robust mechanisms are in place to mitigate risks and maintain regulatory compliance. The Audit Committee plays a pivotal role in fostering transparency, accountability,

and good governance practices throughout the organization.

Furthermore, the Authority prioritizes staff training and awareness programs to ensure that employees have a strong understanding of their roles and responsibilities within the internal control framework. By promoting a culture of accountability and ethical conduct, we aim to foster a work environment that upholds the highest standards of integrity and professionalism. We are committed to continuously enhancing our internal controls to adapt to evolving regulatory requirements and emerging risks. Through ongoing monitoring, periodic risk assessments, and proactive measures, we strive to maintain the utmost confidence in our regulatory processes and safeguard public and animal health.

Risk Management

Risk management is a fundamental component of the Authority’s commitment to ensuring the safety, quality and efficacy of medicines. In the year under review, the Authority took significant strides towards bolstering our risk management practices, including the establishment of a dedicated Risk Management Committee. While the committee is yet to have its inaugural meeting, its formation signifies our proactive approach to risk identification, assessment, and mitigation. We are confident that its establishment will strengthen our risk management practices. The committee’s insights and recommendations will enable us to proactively address emerging risks,

enhance regulatory compliance, and safeguard public health.

The Risk Management Committee will play a crucial role in driving our risk management framework and collaborate closely with Management to identify and evaluate potential risks associated with our regulatory activities, both at the operational and strategic levels. The committee’s collective expertise will enable comprehensive risk oversight across the organization. Additionally, the Risk Management Committee will work in close coordination with other internal functions, such as the Internal Audit Unit and the Audit Committee, to ensure a cohesive and integrated approach to risk management. We remain committed to continuous improvement in our risk management practices and the effective functioning of the Risk Management Committee. By fostering a culture of risk awareness and proactive risk management, we aim to enhance our ability to identify, assess, and respond to risks in a timely and effective manner, ensuring the continued protection of public and animal health.

Deloitte Tip-offs Anonymous

The Authority is committed to promoting a culture of integrity, transparency, and ethical conduct. As part of its efforts to maintain strong governance and effective risk management, the Authority subscribes to Deloitte’s Tip-Offs Anonymous reporting mechanism. This confidential and secure platform allows employees, stakeholders, and members of the public to report any concerns, suspicions, or potential misconduct related to regulatory activities. This platform ensures that any information provided is treated with the utmost confidentiality and is accessible only to authorized personnel responsible for investigating and addressing reported matters.

A Fraud Management Committee is in place to receive Deloitte’s Tip-Offs Anonymous incident reports and in addition to that there are two separate Committees for first and second-level escalation of the tip-offs incident reports in the event that members of the Fraud Management Committee are implicated. The information obtained through this reporting mechanism helps

the Authority to identify and address potential risks, misconduct, or non-compliance promptly and effectively. It enables maintenance of the highest standards of governance, upholding public trust, and protection of public and animal health.

To support these services the Authority has also developed the Whistleblowing and Anti-corruption policies that provide clear guidance

for the reporting of such matters, to ensure that all improper, unethical and inappropriate behaviour is identified and challenged at all levels of the organization. By fostering a culture of accountability and open communication, the Authority collectively works towards maintaining the integrity and effectiveness of regulatory processes.

▶ Licensing & Enforcement (LED)

Introduction

During the year 2023, the Licensing and Enforcement Division continued to execute its duties through the following activities, and more:

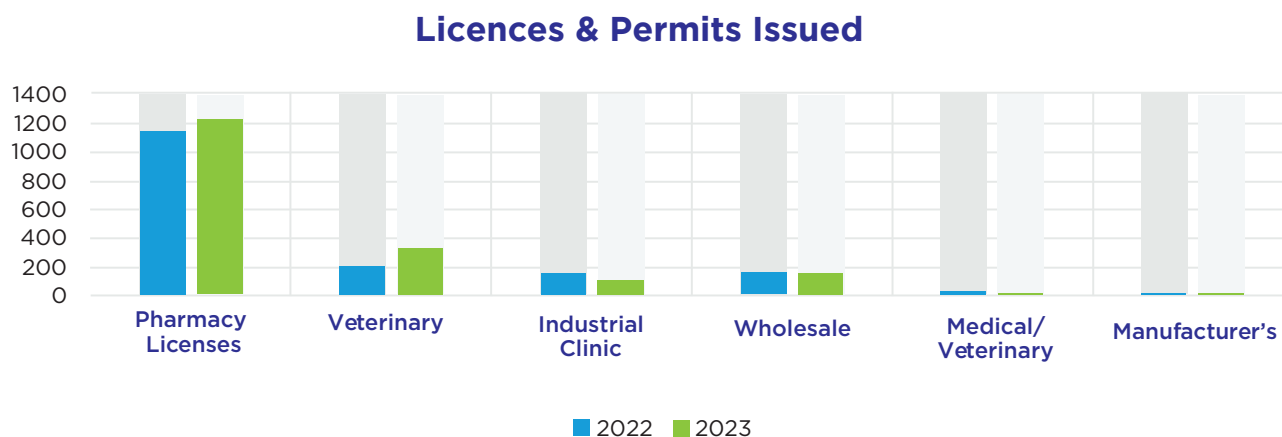
1. Licensing of premises and persons (Issuance and renewal of licences to qualified professionals (pharmacists, doctors, and nurses to dispense medicines legally).
2. Enforcement: Ensuring compliance with the regulations and investigating any violations (Collaborations with law enforcement agencies to monitor unlawful sale and distribution of medicines).
3. Import and Export Control (Collaborating with ZIMRA and Port Officials in clearing medicinal consignments and managing the inflow of medicines through ports of entry).
4. Quality Assurance: Monitoring and maintaining standards of practice.
5. Public Safety: Protecting the public by overseeing safe and ethical practices.
6. Education and Training: Providing ongoing training for stakeholders.

The Licensing and Enforcement Division is comprised of pharmacists, pharmacy technicians, veterinarians and an administrative support team. The work of the Division directly affects public health and the quality of healthcare services. By regulating professionals and enforcing standards, the Division contributes to a well-functioning healthcare system.

Table 1: Licensing of Premises

Licences and Permits	2022	2023
Pharmacy licences	1146	1227
Veterinary Medicines General Dealers 'permits	207	331
Industrial Clinic licences	155	106
Wholesale Dealers' permits	157	155
Medical/veterinary practitioners' licences	30	20
Manufacturer's licences	16	18

Graph 1: Licensing of premises



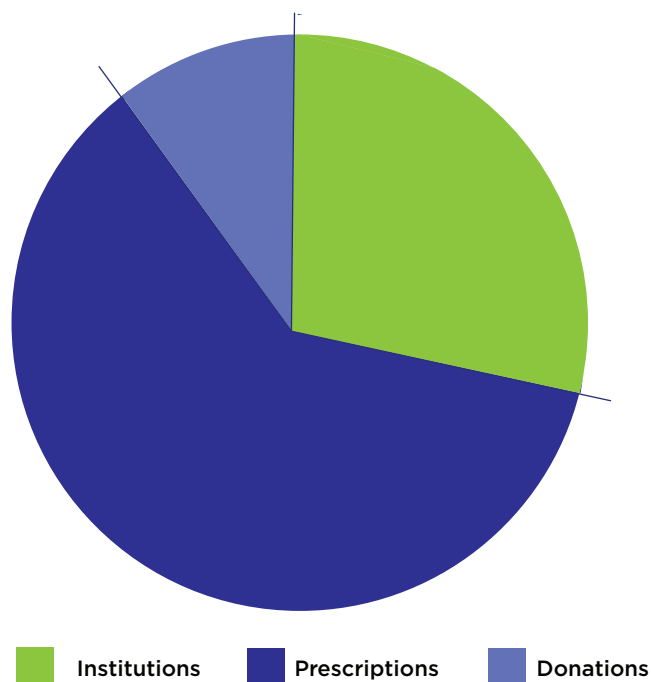
The Authority witnessed an increase in the licensure of pharmacies from one thousand one hundred and forty-six (1146) in 2022 to one thousand two hundred and twenty-seven (1227) in 2023. Two (2) new manufacturers were licensed in 2023, bringing the total cumulative for manufacturers to eighteen (18). 2023 however witnessed a decline in licences issued for dispensing medical practitioners.

Table 2: Authorisation of importation of unregistered medicines

Section 75 Authorisations	2022	2023
Institutions	438	336
Prescriptions	944	1294
Donations	154	58

Graph 2: Authorisation of importation of unregistered medicines

Importation of Unregistered Medicines



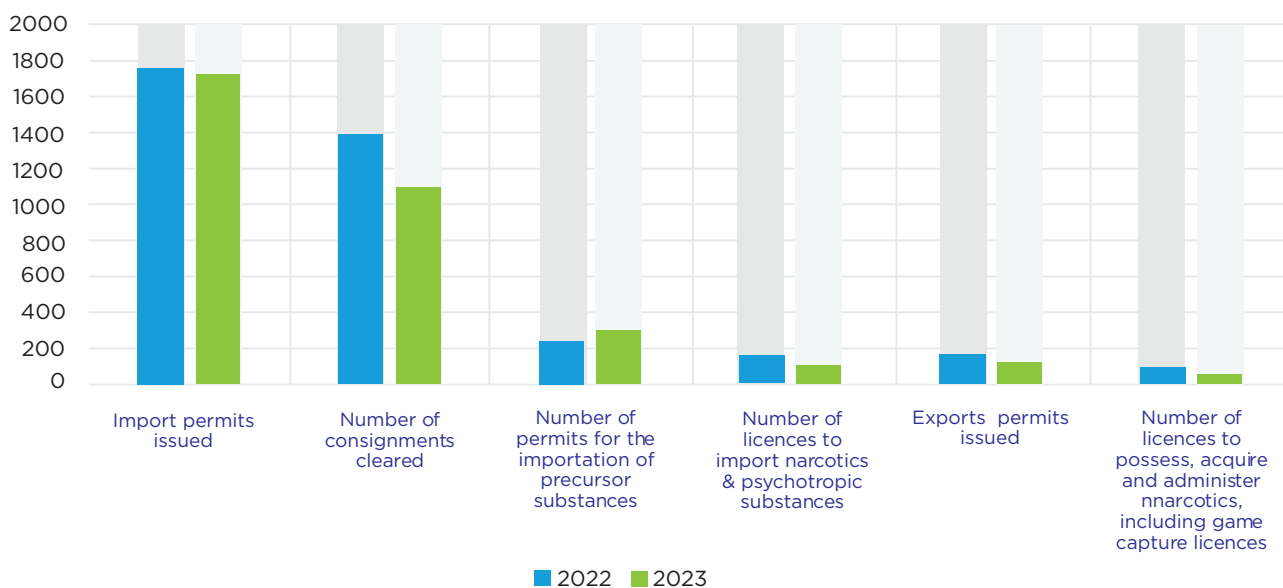
2023 witnessed a significant decline in the number of Section 75 applications received and processed for institutions. There was however an increase in applications processed for individual prescriptions. The increase in applications for individual prescriptions was attributed to an increase in retail pharmacies resorting to apply for individual prescription medicines due to shortages in the supply chain.

Table 3: Import and Export

Administrative Issues	2022	2023
Import permits issued	1758	1726
Number of consignments cleared	1394	1094
Number of permits for the importation of precursor substances	233	301
Number of licences to import narcotics and psychotropic substances	162	108
Export permits issued	170	123
Number of licences to possess, acquire and administer narcotics, including game capture licences	90	50

Graph 3: Import and Export

Clearance of Consignments



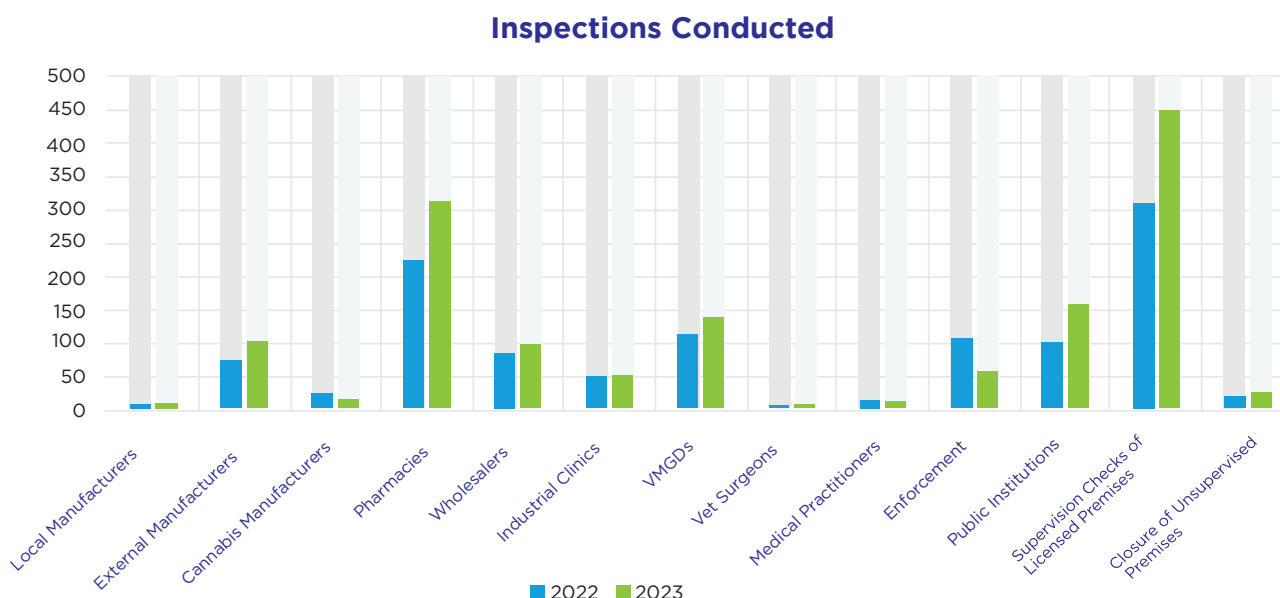
The increase in applications for the importation of precursor substances was attributed to training which was administered to port officials. Consignments found without authorisation letters were made to regularise in retrospect. This process helped in ensuring compliance with regulations even when oversights occurred. Effective control of precursor substances is essential in combating drug trafficking and protecting public health.

Table 4: Enforcement Activities – Inspections Conducted

Premises Type	2022	2023
Local Manufacturers	9	10
External Manufacturers	74	103
Cannabis Producers Inspections	25	16
Pharmacies	225	313
Wholesalers	86	98
Industrial Clinics	51	52
VMGDs	115	139
Veterinary Surgeons	7	9
Medical Practitioners	15	13
Enforcement	107	59

Public Institutions	101	158
Supervision Checks of Licensed Premises	311	450
Closure of Unsupervised Premises	20	26

Graph 4: Enforcement Activities – Inspections Conducted



There was a notable increase in inspections of licensed premises from 2022 to 2023. The impact of Covid-19 on the Authority’s operations in 2022 likely influenced this trend. The need for post-marketing sampling and surveillance led to inspections of one hundred and fifty-eight (158) public institutions.

Good Manufacturing Practice Inspections

The division conducted inspections for a cumulative total of one hundred and three (103) external manufacturers in the year 2023. The inspections were aimed at supporting new product registrations and continued product registration, and a total of seventeen (17) as part of reliance mechanisms. A total of three (3) submissions were cleared through the desk review process. The division engaged the facilitative regulatory pathways through assisting in the setup of greenfield facilities and this saw the licensing of one (1) human allopathic medicine manufacturer and one (1) complementary medicine manufacturer. The GMP office conducted a quality circle with the industry in 2023. Key issues concerning Heating and Ventilation and Air Conditioning of facilities, Equipment qualifications, process validations and analytical method development amongst other key topics were discussed.

The division continued providing advice on technical requirements for setting up of greenfield facilities to potential investors in line with the NDS1 2021 to 2025 and the Pharmaceutical Manufacturing Strategy 2021 to 2025.

The division terminated the local industry’s roadmaps to GMP compliance in the year after having had these for seven years as initiatives of the AUDA NEPAD and PMA with regulatory oversight from MCAZ. All local manufacturers are expected to fully comply with Good Manufacturing Practices.

Key milestones achieved include the following:

- The division managed to ensure that all the facilities that were referred from the Evaluation and Registrations Division for inspection were inspected within set timelines and there was no backlog.
- All the local manufacturing units were inspected within the stipulated 12 to 18 months timelines.
- Three (3) of the manufacturing facilities were now meeting the minimum cGMP requirements and were operating at acceptable levels and the rest were showing a positive trajectory for attaining the minimum level of cGMP.
- One local manufacturer was inspected under the

SADC harmonisation program (Zazibona) and was found operating at acceptable levels of cGMP.

- e) The division hosted numerous meetings with Cannabis oil extractors and finished Cannabis oil manufacturers, resultantly, two already meet minimum GMP requirements and were licensed.

Lessons Learnt:

- i. The local industry continued to face challenges of CAPEX for facility upgrades.
- ii. The Authority continued to lose experienced inspectors to the local manufacturing industry.
- iii. There was a need of continuously bridging the information gap between the local industry and the regulators through quality circles and more frequent inspections.

Zazibona

The division continued to implement the Zazibona inspections which are one of the success stories of harmonisation in the African region. The Authority managed to plan and execute the inspection of 17 blocks in 2023 and a cumulative of 9 desk reviews were received, processed, and closed.

Inspectors from MCAZ participated in various capacities as Lead inspectors and co-inspectors in these harmonisation inspections. The inspectors also participated in the first Quality Circle with the SADC manufacturing industry.

The Zazibona crafted its new 5 years strategic plan and the division staff participated in the processes. The new plan involves central submission of dossiers and central evaluation with central metrics monitoring. The division was involved in the development of the user requirements specifications for the new systems and the development of the standard operating procedures.

Good Supply And Distribution Practice Inspections

All wholesale dealers were inspected before renewal in line with World Health Organisation (WHO) Global Benchmarking Tool requirements. This also followed the need to assess for compliance with the updated Good Supply and

Distribution Practices (GSDP) Guidelines. The Authority conducted a virtual stakeholders training on temperature mapping which was a common observation during inspections of wholesale dealers. Temperature mapping is crucial for ensuring the proper storage and transportation of pharmaceutical products, especially those that are sensitive to temperature variations. There was a general improvement in the quality management systems by the wholesalers.

Post Marketing Surveillance (PMS)

Post Marketing Surveillance (PMS) is a regulatory function meant to continuously monitor the quality, safety and efficacy of pharmaceutical products on the market at all levels of the supply chain. A total of 545 samples were collected for post-marketing surveillance and testing. Samples were taken from different stages of the supply chain from pre-distribution up to end user level in public clinics. Seven (7) samples failed analysis, and these were all products that had been sampled as suspected substandard products. There was a total of nine (9) product defects that were received during the year. Five (5) of the received product defects were products manufactured locally whilst the other products were being manufactured out of the country.

WHO Global Bench Marking (GBT)

Following the 2021 WHO assessment, the division continued to work on addressing IDPs raised. All divisional key processes were automated. Generally, the Division remained committed to upholding high standards of quality and compliance in its operations. Market Control Function and Licensing functions were confirmed to have reached maturity level 3 (ML). The regulatory inspections function was confirmed to have reached ML2 with four(4) outstanding IDPS. The Inspectorate continued to work hard to achieve ML3

MCAZ PIC/S Pre-Accession Application

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any Authority having a comparable GMP inspection system. PIC/S presently comprises of fifty-six (56) Participating Authorities

from all over the world (Europe, Africa, America, Asia and Australasia).

The mission of PIC/S is to lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products.

The Medicines Control Authority of Zimbabwe (MCAZ) initiated the process of attaining full PIC/S membership by submitting a pre-accession application in November 2023. Attaining PIC/S membership will be a demonstration of comparability between the MCAZ GMP inspection system and GMP inspection systems in other parts of the world. This will open export opportunities for Zimbabwe's domestic pharmaceutical manufacturers.

The MCAZ's pre-accession application was tabled at the PIC/S Committee meeting held in Bangkok, Thailand on the 6th and 7th November 2023. A positive response was received confirming approval to participate in PIC/S pre-accession.

Plans For the Future:

- i. The Division hopes to attain WHO Global Benchmark Level 3 by the end of 2024 for the outstanding Regulatory Inspections function.
- ii. In view of the high staff attrition rates, the Division embarked on creating an eLearning Centre. This should be finalised by mid-2024.
- iii. To ensure that more local manufacturing facilities attain the minimum level of cGMP and can expand and export into the region.
- iv. To ensure that the Authority retains its key trained inspectors.
- v. To do more quality circles to ensure capacity building for local industry.
- vi. To be a centre of regulatory excellence for GMP inspections.
- vii. To facilitate the entrance of new greenfield manufacturing facilities.
- viii. To continue engaging potential investors and familiarise them with the requirements for setting up facilities in Zimbabwe.

▶ Medicinal Cannabis in Zimbabwe

Background

The Licensing and Enforcement – Cannabis Desk was formed in 2018 to administer the S.I. 62 of 2018 on behalf of the Ministry of Health and Child Care. This encompasses matters on new applications for licence sites, applications for renewal, variation or amendment of licences for sites or persons, the production, handling, import and exportation of controlled substances and all compliance issues relating to controlled substances.

Cannabis licences issued

The S.I. 62 of 2018 provides for two types of licences:

- i. **Cultivation and Research of Cannabis** (*Research and Development*).
- ii. **Cultivation and Production of Cannabis** (*Production for export purposes as well as Research & Development activities*)

The Cannabis produced is currently for **export purposes only**. Local use of Cannabis **produced in Zimbabwe** can only be for **research and development** purposes.

A total of sixty (60) production of Cannabis for medicinal and scientific use licences had been issued by the end of 2023. Fifty-nine (59) licences were active with fifty-seven (57) licences being for cultivation and production and two (2) cultivation and research licences. The first licence was issued in 2019, and these licences had a validity period of five (5) years.

CANNABIS LICENCES ISSUED

2019	2020	2021	2022	2023
35	12	10	2	1

General Summary of all Cannabis Cultivation Sites

Site level of description	Number
Number of sites with Cannabis plants witnessed during inspections	5
Number of sites focusing on Industrial Hemp in the interim with plants witnessed during inspections	5
Number of sites visited with no development activities yet	19
Number of sites with construction activities in progress	14
Sites that are licensed but are still to be inspected by MCAZ, some of which the licensed sites are not known by the Authority	13
Number of sites with research licences and focusing on Industrial Hemp research	2
Number of licences surrendered/revoked	1

Site level of description	Number
Number of licences temporarily suspended	1
Total Number of licences issued	60

Import and Export of Cannabis

In 2023 Zimbabwe recorded its first commercial export of medicinal Cannabis. The dried cannabis flower was exported to Europe.

Challenges Affecting the Medicinal Cannabis Sector.

No.	Challenges/ obstacles	Efforts made to address them
1.	Government policy to partner all investors and execute the project on Government owned land so as to have an overall oversight of the sector amid fears of abuse and possible pilferage into the illicit market. Investors confidence was shaken by this approach.	The policy was removed in a letter dated 20 th May, 2020 which enabled 100% ownership of medicinal cannabis licences as well as giving investors an option to utilize privately owned land.
2.	Disagreements between the Government and investors regarding royalty and taxation frameworks.	The Zimbabwe Investment and Development Agency, through the Ministry of Finance came up with Tax regulations that were welcomed by the investors.
3.	Early challenges noted were to do with several courier companies and airlines that were hesitant to ferry medicinal cannabis products.	The Authority made efforts to engage these companies and educate them about the provisions of S.I. 62 of 2018 and received a positive response.
4.	Absence of a local market for medicinal cannabis products. This has led to most licence holders halting production activities amid fears of failure to get an export market.	The Authority is currently consulting several stakeholders to explore the possibility of local use and outdoor cultivation of medicinal cannabis. Work in progress.
5.	The industry was split over indoor and outdoor cultivation	

Approval of Hemp-Based Cannabidiol (CBD) Products as Complementary Medicines

In 2022, the Authority published two (2) Circulars, Circular 17 of 2022 and Circular 20 of 2022, which advised stakeholders that the Authority will consider applications for approval of Hemp-based cannabidiol (CBD) products as complementary medicines.

One (1) processing site was issued with a pharmaceutical manufacturer's licence restricted to complementary medicines manufacture (CBD distillate, Isolates and finished products containing CBD).

► Evaluation and Registration (EVR)



Introduction

The Evaluations & Registration Division (EVR) is responsible for the assessment of the quality, safety and efficacy of human, veterinary, and complementary medicines. The assessment teams consist of pharmacists, veterinarians, and scientists and their work is supported by a small administrative team. The Division has two major functions namely the pre-registration and the post-registration function. The pre-registration function is comprised of teams responsible for assessment of applications for marketing authorisation whilst the post registration function teams process variations and re-registration of medicines.

Activities

The Division has continued to track applications, which are handled by a dedicated administrator, to enhance timeliness and remove products from

applicants who have not responded. As a result of this approach, which encouraged timely responses, sixty-seven (67) were closed, and hundred and seventy-six (176) were registered. The full pipeline of pending registration applications presented significant challenges, with only minor improvements observed following the completion of product applications.

In line with the Authority's strategic plan for 2022 to 2026 to fully automate key business processes, EVR developed a User Requirements Specification (URS) for its database that aims to enable the ICT Unit to automate the processing of registration applications. The key features of the URS include an online submission platform, end-to-end tracking of applications for registration from the receiving, screening, first and second evaluation and the final regulatory decision processes. The URS on EVR's database will also automate the variations and the

re-registration (marketing authorization renewal) processes. In 2024, EVR plans to implement the streamlined processing of all registration applications, communicated in Circular 26 of 2023. This process aims to improve efficiency on medicines registration by screening applications within ten (10) working days of receipt, limiting review (evaluation) circles to a maximum of two (2) and reaching regulatory decisions within nine (9) months of MCAZ time.

Effective January 2023, all product registrations (human, veterinary and complementary medicines) now have a validity period of five (5) years from the initial date of registration. Applications for re-registrations of human allopathic medicines were first received by the EVR Division in February 2023 and the Division commenced assessment of these applications in the same month. From February 2023, the Authority waived fees for processing re-registration (marketing authorisation renewals) until December 2023 to encourage applicants to regularise with the new regulatory requirement.

Human Allopathic Medicines

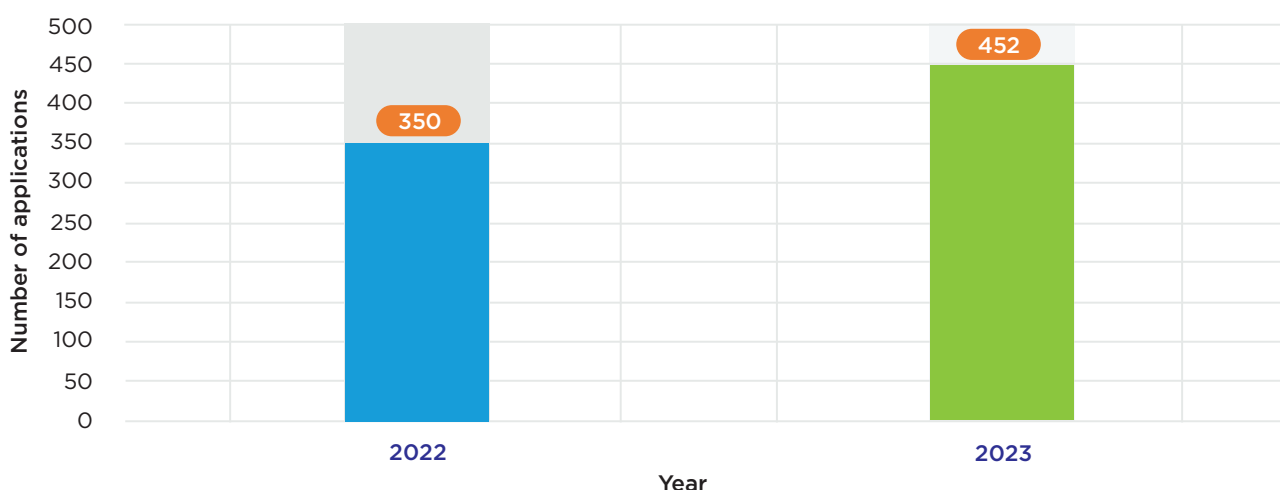
Pre-Registration Highlights

Applications For Registration

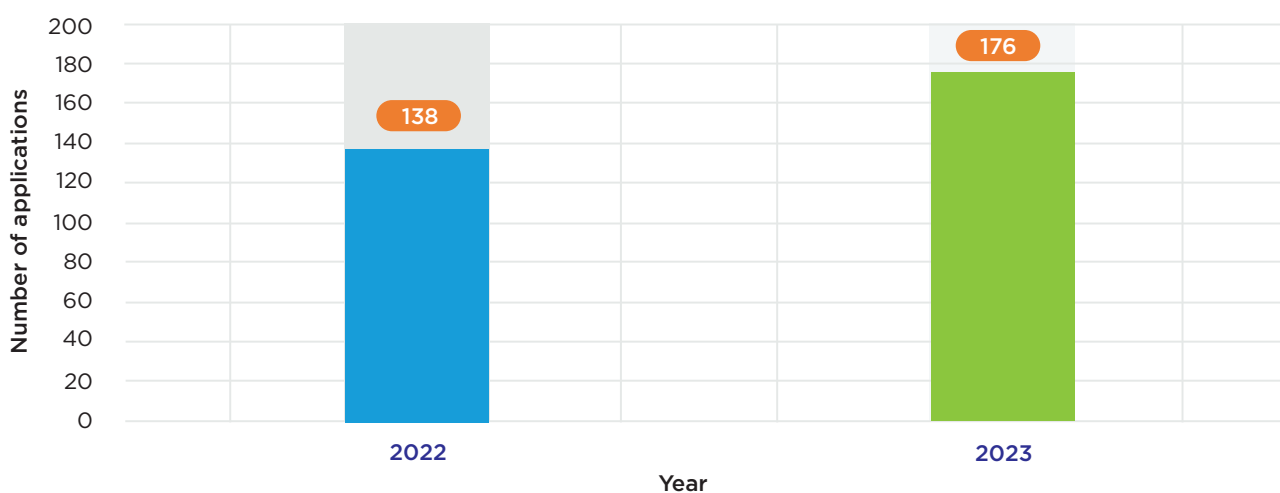
Received	Registered	Refused	Withdrawn
452	176	67	15

Trend analysis (2022 vs 2023)

Comparison of applications received 2022 vs 2023



Comparison of applications registered 2022 vs 2023



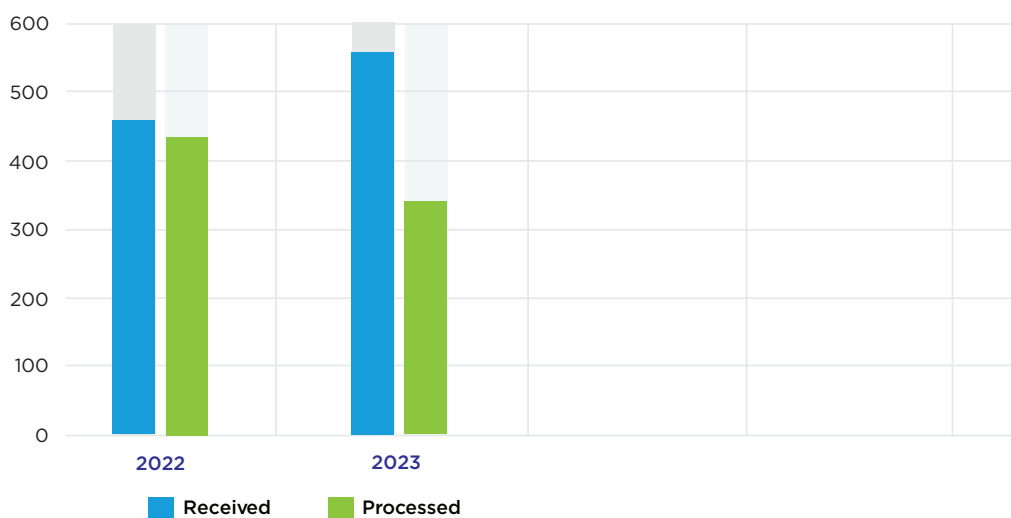
Post-registration Highlights

Post-approval Variations

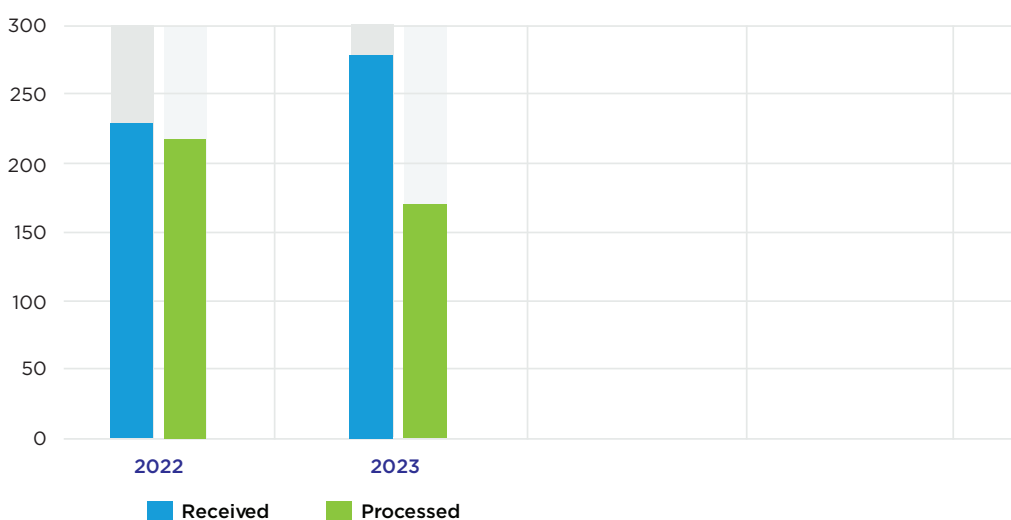
Variations received	Variations Processed	Variation Responses Received	Variation Responses Processed
557	340	210	171

The Division processed 61% of the variations and 81% of the responses to variations that were received in 2023. This is a notable decrease from the 96% variations processed in 2022 due to staff attrition between February 2023 and May 2023. These officers were replaced in August 2023.

Variations applications

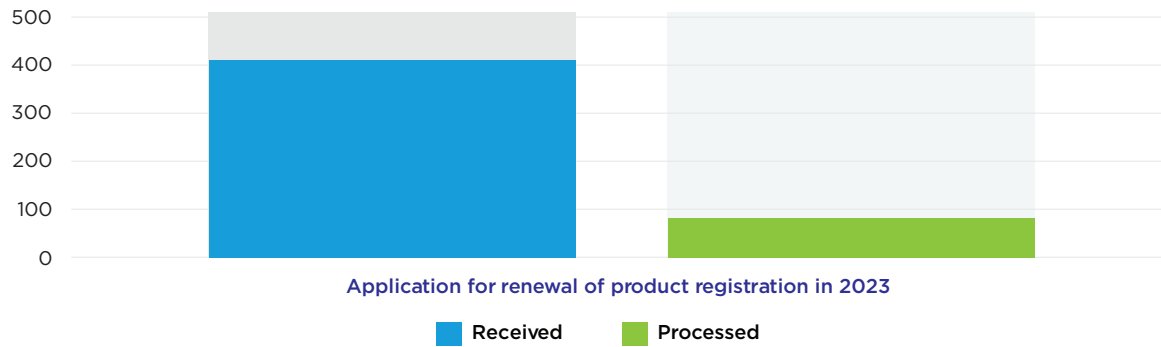


Variations responses

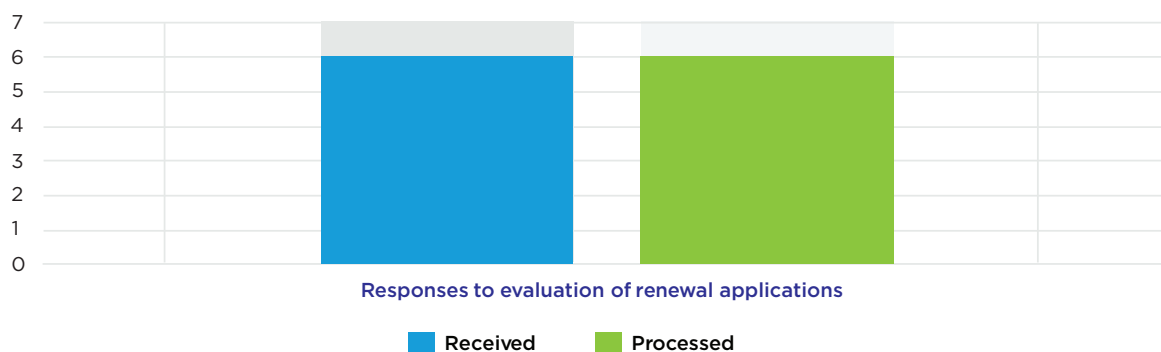


Re-registrations received	Re-registrations processed	Re-registrations Responses received	Re-registrations Responses processed
409	80	6	6

New re-registrations applications



Reregistrations responses



Capacity Development Issues Undertaken.

Key/Notable Achievements

The Division was able to implement the WHO Global Benchmarking exercise's recommendations for re-registrations to reach maturity level 3. According to the benchmarking tool, a national regulatory authority should grant market authorisation for a product with a limited validity period and the market authorisation can be renewed before the product is re-introduced into the market after a quality review. This measure ensures that the product quality is maintained throughout the product's life cycle. The Division processed 20% of re-registration applications received in 2023. Furthermore, 100% of all responses received in 2023 were processed and finalised.

Lessons Learnt and Challenges

The EVR Division continued to experience **staff retention issues**, a perennial problem that proved to drag progress in the timely registration of medicines. The Division lost five (5) officers, two (2) of whom were highly experienced senior assessors who tendered resignations by December 2023. EVR management plans to replace human capital timeously and automate training in 2024 by introducing e-learning courses that offer in-house training and additional training offered by development partners such as WHO, USP, GHPP and others. These two measures will mitigate the high risk of staff attrition.

EVR recorded a 29% **increase in new applications for registration** of allopathic human medicines in 2024. The statistics reveal that 350 new applications for human allopathic medicines were received in 2022 against 452 new applications for human allopathic medicines that were received in 2023. There has been a steady growth in registration applications (approximately 100%) from the years 2020 to 2024 without change in the staff compliment in the Division. This phenomenon has affected the efficiency of the Division amongst other factors. In 2024, the Division plans to prioritise screening of new applications for registration within ten (10) working days of receipt, limit the number of review cycles to a maximum of two (2) and track the final regulatory decision.

Plans For the Future.

The Division plans to attain World Health Organisation (WHO) **Global Benchmarking Tool (GBT) Maturity Level 3 (ML3)** for the Registration and Marketing Authorisation (MA) function in 2024. In order to attain this milestone

EVR is required to ensure that the re-registration otherwise known as periodic renewals of registered medicines is implemented to majority of registered products. At the previous WHO audit, the Division had attained ML2 at 92% implementation of the MA function according to the computerised GBT.

EVR plans to use the assistance of the Information and Communication Technology (ICT) Unit of the Authority to **automate key regulatory procedures** to improve efficiency and streamline operations. As a result, the Division plans to have a new Zimbabwe Drug Information System (ZIMDIS) that allows online

submission and efficient tracking of new registration applications.

Furthermore, EVR plans to explore various avenues under the **MCAZ Reliance Framework** and the WHO Guidelines on Good Reliance Practices (GRoP) to process registration applications. These measures may include but are not limited to enhancing collaboration with like regulators globally (signing MoUs with strategic National Regulatory Authorities e.g., Egypt, South Africa, Iran etc), timely access to safe, effective and quality medical products, focus on value-added regulatory activities such as post-marketing authorisation on products approved using risk-benefit approaches.

▶ Evaluations & Registration: Veterinary Unit

Introduction

Activities

The Unit continued collaboration with local stakeholders every quarter, ensuring alignment with industry needs and priorities. In addition, the Unit fostered strategic partnerships and continued participation in the Veterinary Medicines Zazibona Collaborative procedure, enhancing regional collaboration and knowledge sharing.

Focus on Notable Changes and Developments.

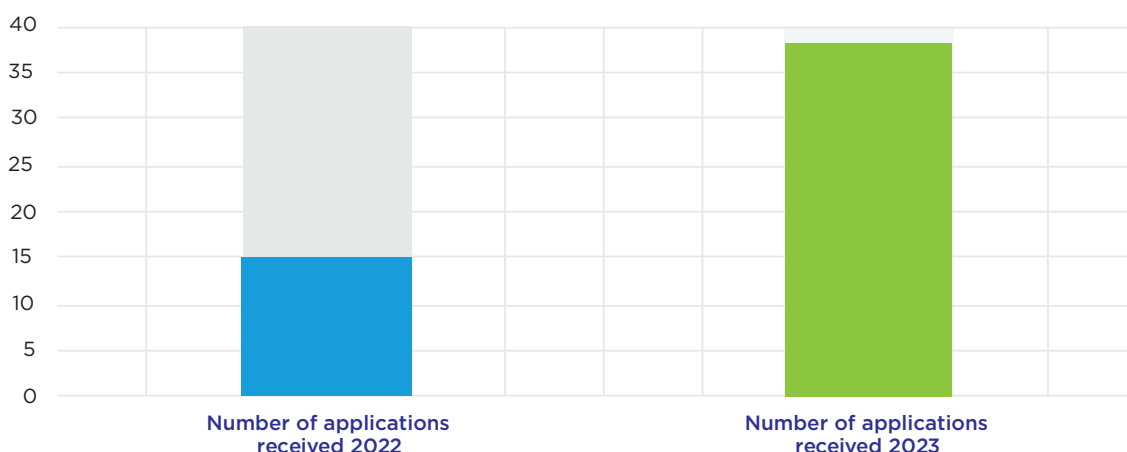
Applications for Registration

Received	Registered	Refused	Withdrawn
38	11	7	3

The Unit recorded a 253% increase in applications received from the previous year. Two dipping trial protocols were assessed and approved during the same year. Processing of applications was faster compared to the previous year, showcasing enhanced efficiency and streamlined processes due to implementation of the MCAZ Reliance Framework on processing applications for registration.

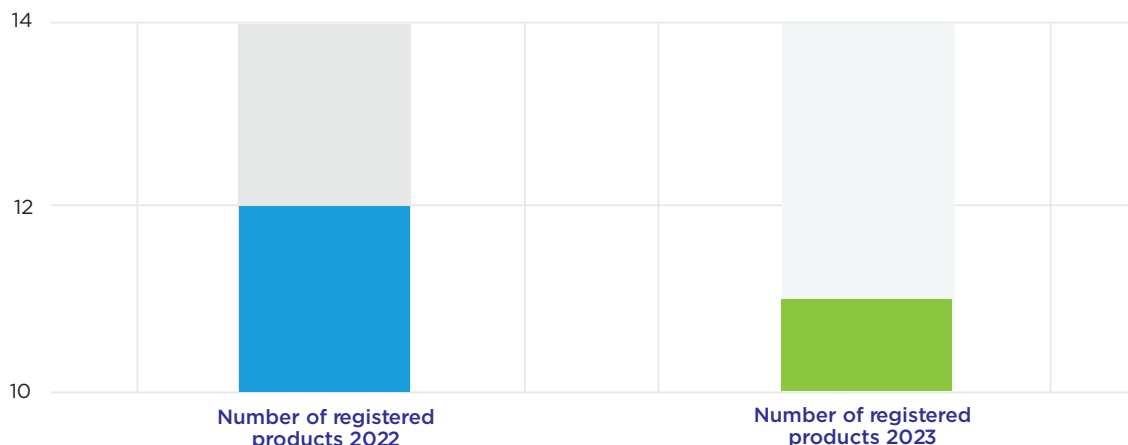
Trend analysis (2022 vs 2023)

Comparison of Applications Received 2022 vs 2023



Graph 1 shows a 253% increase in applications received in 2023.

Comparison of Registered Products 2022 vs 2023



Graph 2 shows an 8% decrease in products registered in 2023.

Post-approval Variations

Variations Received	Variations Processed	Variations Responses Received	Variations Responses Processed
55	36	18	16

The Division processed 65% of the variations to registered veterinary medicines that were received in 2023. Furthermore, 88% of the responses to variations received were processed in the same period.

Capacity Development Issues Undertaken.

Key/Notable Achievements

By developing and implementing guidelines on post-authorisation variations for veterinary medicinal products, the Unit significantly improved the efficiency and effectiveness of processing applications for amendments. These guidelines not only clarified requirements for applicants but also enabled our team to review applications more consistently. As a result, the Division achieved a reduction in processing time and an increase in application compliance rate. This enhancement in the evaluation process has facilitated the clearing of the backlog and fostered a more transparent and predictable regulatory outcome.

Plans For the Future.

The Division plans to volunteer in the pilot Veterinary Global Benchmarking Tool (GBT) self-assessment being implemented by the United Kingdom Veterinary Medicines Directorate (UKVMD) and the World Organisation for Animal Health.

▶ Evaluations & Registration: Complementary Medicines Unit

Introduction

The Complementary Medicines Unit is a sub-unit of the Evaluations and Registration Division and is responsible for the assessment, pre-registration, and post-registration of complementary medicines.

Activities

The unit convened a meeting with the Traditional Medicines Practitioners Council of Zimbabwe (TMPCZ) to explore future collaboration and the potential inclusion of traditional medicines within the unit's scope. Subsequently, a memorandum of agreement will be signed between MCAZ and TMPCZ in early 2024, formalizing the partnership and joint endeavours. Furthermore, the team engaged in meetings and correspondence with multiple applicants to enhance their understanding of the range of products covered by the Complementary Medicines Unit. These interactions also focused on elucidating the assessment and approval processes for the benefit of the applicants.

Focus on Notable Changes and Developments.

In 2023, the Unit experienced a slight decrease in dossier submissions compared to previous years. In 2022, a total of sixteen (16) local applications were submitted, with four (4) applications approved by the third quarter of 2023. However, no new local applications were received in 2023.

During the fourth quarter of 2023, a product mapping exercise was conducted to monitor the status of applications in the registration pipeline. It was observed that many local products, which had previously been issued an intent to refuse approval, did not respond in time. The predominant challenges were related to their facilities failing to meet the requirements of current Good Manufacturing Practices.

At the 44th and 45th meetings held in October and December 2023 respectively, the Sub-Committee for Complementary Medicines acknowledged GMP-related issues with herbal product applications from local applicants and engaged the MCAZ inspectorate. In response, the Licensing and Enforcement Division is currently developing guidelines to assist these local applicants.

Furthermore, during the 40th meeting in December 2022, the Complementary Medicines Sub-Committee members reached a consensus that CBD-based products would not be approved without analysis from the MCAZ laboratories for delta-9-THC and CBD content. Despite receiving thirteen new CBD-based product applications, only one product was able to meet the revised THC limits prescribed in the amendment of the Criminal Law (Codification and Reform) Act Chapter 9:23, which stipulates a maximum THC content of 1.0%.

TREND ANALYSIS

Table 1.1 Retrospective analysis of Applications received.

Period	2020	2021	2022	2023
January	0	2	15	5
February	0	3	4	14
March	2	4	19	12
April	2	9	3	12
May	3	5	19	31
June	0	23	14	11
July	6	11	9	3
August	5	10	19	3
September	6	11	14	25
October	5	4	10	5
November	4	9	11	20
December	10	9	14	1
Total	42	100	151	144

From Table 1.1 and Figure 1.1, it can be noted that the year 2023 recorded a decrease of **4.64%** in the number of applications received.

Applications received

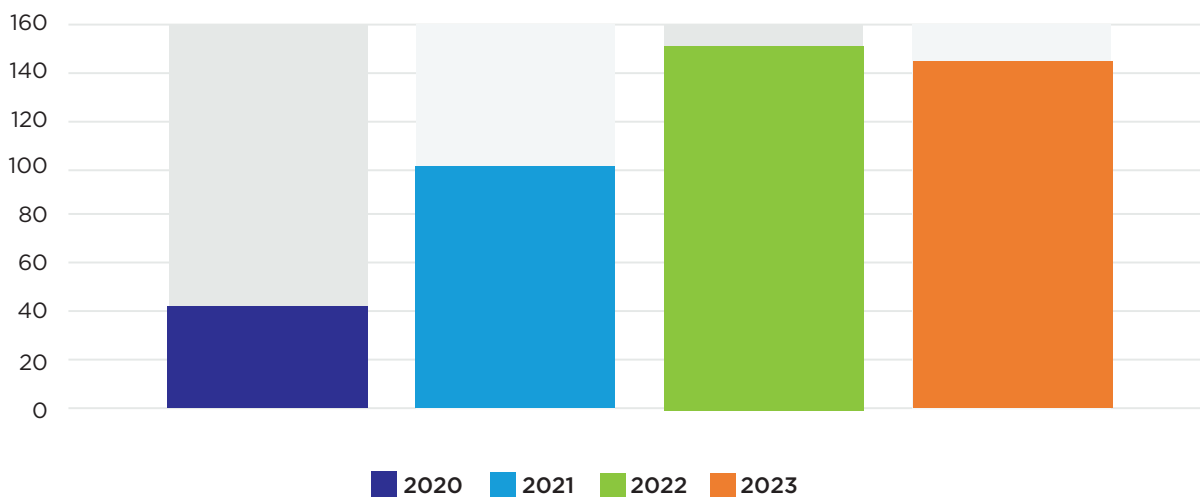


Figure 1.1: Trend analysis of Applications received.

Table 1.2: Retrospective analysis of Applications evaluated.

Period	2020	2021	2022	2023
January	2	7	6	6
February	1	1	0	2
March	0	0	7	12

April	0	13	0	0
May	5	4	13	8
June	0	0	5	4
July	5	8	18	4
August	2	7	3	4
September	2	16	11	14
October	5	5	2	6
November	4	16	11	8
December	0	0	0	0
Total	26	77	76	68

From **Table 1.2** above and **Figure 1.2** below it can be noted that the year 2023 recorded a **10.53%** decrease in the number of applications evaluated over the previous year.

Applications Evaluated

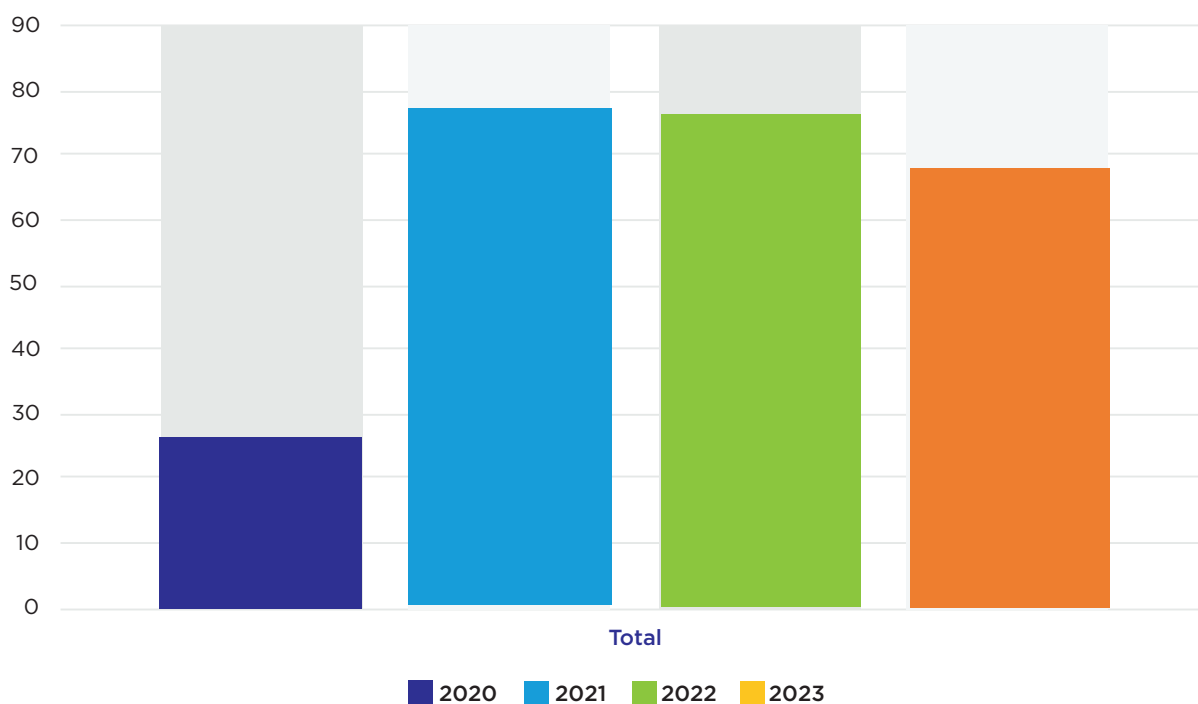


Figure 1.2: Trend analysis of applications evaluated.

Table 1.3 Retrospective analysis of Applications approved.

Period	2020	2021	2022	2023
January	1	0	4	0
February	1	8	16	14
March	2	6	11	0
April	0	0	2	0
May	0	8	0	2
June	10	1	9	0

July	2	5	9	5
August	16	4	0	6
September	0	3	0	12
October	2	4	0	4
November	6	9	3	5
December	2	7	5	0
Total	42	55	59	48

Applications Approved

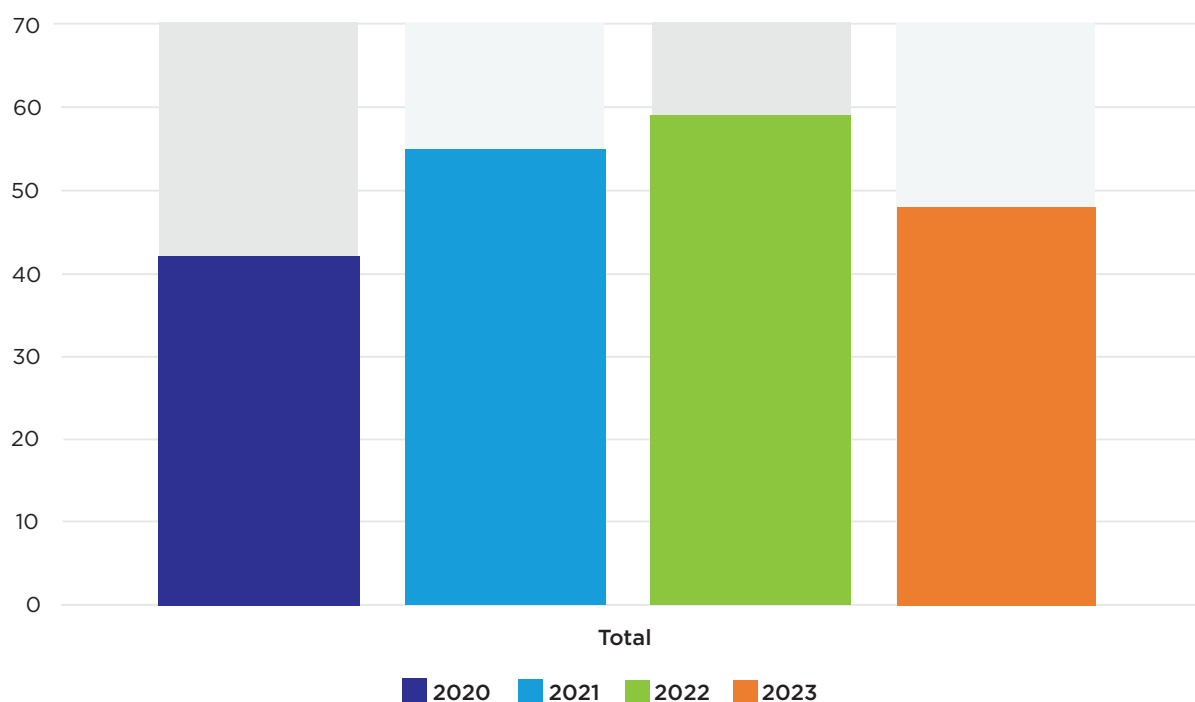


Figure 1.3 Trend analysis of applications approved.

From **Table 1.3** above and **Figure 1.3** below it can be noted that the year 2023 recorded a **18.64%** decrease in the number of applications approved over the previous year.

Key/Notable Achievements

In the first quarter of 2024, the Complementary Medicines Unit received ten (10) new CBD-based product applications from a local applicant, out of which six (6) have been approved. Importantly, the delta-9-THC levels in these products were all below the acceptable limits as prescribed in the amendment of the Criminal Law (Codification and Reform) Act Chapter 9:23, which mandates a maximum THC content of 1.0%.

Additionally, during this period, a memorandum of agreement was signed between the MCAZ and the TMPCZ. This agreement aims to uphold patient and

public safety and confidence in traditional medicines by fostering the exchange of information and the development of regulations for traditional medicine, among other objectives.

Lessons Learnt and Challenges

In the Complementary Medicines Unit, a minor increase in the backlog of new applications was noted. This was attributed to the insufficient number of regulatory officers within the unit, who were overwhelmed by the volume of applications and unable to keep pace with the unit's demands.

To ensure the accurate registration of Zimbabwe's traditional medicines and to enhance patient and public safety, it is imperative to develop regulations and guidelines governing traditional medicines, as well as establish a framework for their registration

separate from supplementary medicines.

Plans For the Future

The unit intends to assist with the registration process and make it run smoothly by participating in Human Medicines Liaison Meetings and hosting stakeholder engagements on the prerequisites for the licensing of complementary medicines.

To address the backlog of new applications and enhance expertise in assessing complex molecules, the Complementary Medicines Unit is planning to conduct staff training and expand its capacity.

Furthermore, to recognize traditional medicines as an accepted means of treating and curing illnesses in Zimbabwe, the unit aims to incorporate the regulation of traditional medicine within the scope of complementary medicines. This initiative also involves the development of Good Manufacturing Practice (GMP) guidelines and regulations that align with local practices and traditions.

Additionally, the unit intends to facilitate the registration process and ensure its smooth operation by actively participating in Human Medicines Liaison Meetings and organizing stakeholder engagements to discuss the prerequisites for licensing complementary medicines.

► Pharmacovigilance and Clinical Trials Division

1. Introduction

1.1 Vigilance

The Medicines Control Authority of Zimbabwe (MCAZ) is the National Centre for Pharmacovigilance and has been a member of the World Health Organisation (WHO) Programme for International Drug Monitoring since 1998. As part of this programme, the MCAZ works together with the other member states to monitor medicines safety and take appropriate action to protect the public. As the national pharmacovigilance centre, the MCAZ identifies signals of medicine safety such as unknown or poorly characterized adverse events in relation to medicine and communicates the information in a way that improves therapeutics and promotes patient safety. Vigilance is a regulatory function that the national PV Centre does in collaboration with MoHCC public health programs, private health sector, healthcare professionals, patients, consumers, pharmaceutical industry, and other partners. Through the National Pharmacovigilance Centre, which is housed in the Pharmacovigilance and Clinical Trials (PVCT) division, the MCAZ also assesses risks and options for risk management and applies information from pharmacovigilance for the benefit of public health programs, individual patients, national medicines policies and treatment guidelines. The current WHO Global Benchmarking Tool Version VI currently expanded the scope of pharmacovigilance to include safety monitoring of all types of medical products to include vigilance regulation functions such as medicines, vaccines, and haemovigilance (safety monitoring of blood and blood products).

1.2 Clinical Trials

All clinical trials conducted in Zimbabwe are regulated in terms of Part III of the Medicines and Allied Substances Control Act [Chapter 15:03] and the Medicines and Allied Substances Control (General) Regulations, 1991. (S.I. 150 of 1991). The Pharmacovigilance and Clinical Trials (PVCT) Division of the Medicines Control Authority of Zimbabwe (MCAZ) has a regulatory oversight function for clinical trials conducted in Zimbabwe. No clinical trials of medicines in Zimbabwe involving human participants should be conducted until the MCAZ has, with the approval of the Secretary for Health and Child Care, authorized the conduct of the clinical trial. The PVCT division receives, processes and evaluates the applications from local applicants (industry, academia and investigators) for approval to conduct the study within Zimbabwe. The division also provides authorization for the importation of study medicines to conduct clinical trials. Any amendments required during the conduct of the study must be approved by the MCAZ.

1.3 Post-registration retentions of medical products, safety variations, benefit/risk communication, medicines safety reviews and recategorizations, and safety-related products defects and recalls.

In addition to the pharmacovigilance activities and clinical trial authorisations and monitoring, the Pharmacovigilance and Clinical Trials (PVCT) division is responsible for the following functions;

- 1.0.1 Processing post registration retention fees for registered medicines, both human products and veterinary products.

- 1.0.2 Processing of post-registration safety variations and applications for promotional materials.
- 1.0.3 Benefit-risk communications: Medicine, vaccines and haemovigilance information dissemination through publishing medicine information bulletins, manuscripts publications, circulars, and alert notices.
- 1.0.4 Medicines safety reviews and re-categorisations.
- 1.0.5 Processing product defects and recalls related to safety aspects although post marketing surveillance of quality and efficacy i.e. market control is done by the Licensing and Enforcement Division.

2. Focus on Notable Changes and Developments.

2.1 Vaccines vigilance - Improved AEFI VigiMobile and VigiFlow reporting tools successful deployment from April 2023 to date.

The AEFI VigiMobile application and VigiFlow system for AEFI reporting were deployed countrywide on the 17th of April 2023. AEFI VigiMobile is an application specifically developed by the Uppsala Monitoring Centre (UMC) for AEFI field reporting. Immunisation workers can use it to collect data on their smartphone or other mobile device even when they are offline. VigiFlow allows the reporting of AEFIs (from the district to the national level allowing supervisors to review, monitor and process the data on the national database (VigiFlow).

A series of AEFI VigiMobile and VigiFlow – train-the-trainer trainings were conducted from 28th February, 2023 to 28th March, 2023. A total of 480 healthcare professionals from the national level, the ten (10) provinces and the sixty-three (63) districts were trained on how to use these tools in-order to improve the AEFI reporting system in Zimbabwe. These national, provincial and district level trainings were funded by CDC, WHO and AFENET. The MCAZ with financial support from GF/UNDP also conducted provincial AEFI VigiMobile – VigiFlow pharmacovigilance trainings in four (4) provinces (Matabeleland North, Matabeleland South, Midlands and Masvingo) in November 2023.

The Zimbabwe “live” VigiFlow for vaccines safety AEFI reporting system for use by healthcare professionals can be accessed using the following link: <https://vigiflow.who-umc.org>.

The Zimbabwe “live” VigiMobile for vaccines safety AEFI reporting app for use by healthcare professionals can be accessed using the following link: https://vaccine-primaryreporting.who-umc.org/zw_aefi.

The AEFI VigiMobile application can also be downloaded using the QR codes below:



OR



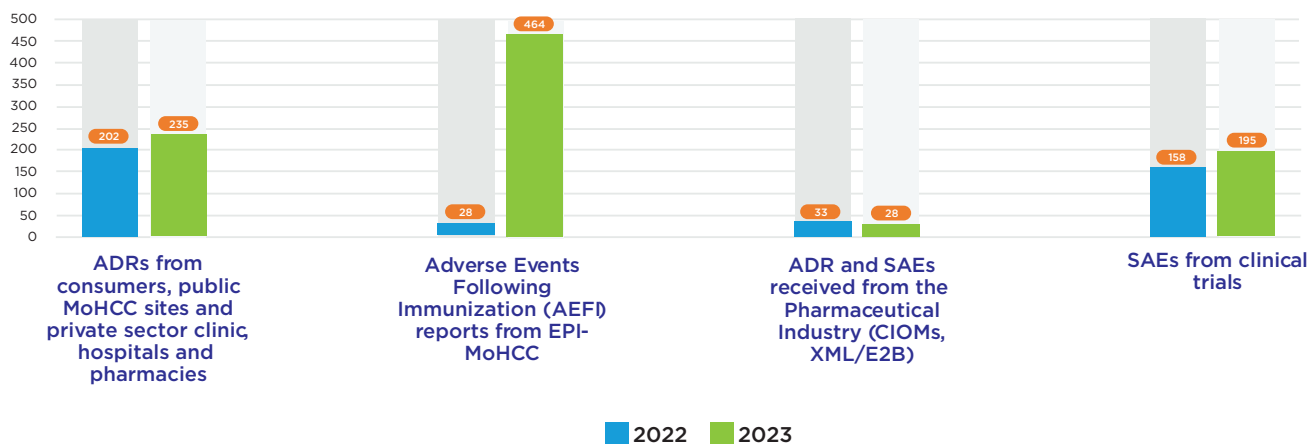
2.2 Overview of Individual Case Safety Reports (ICSRs) (ADRs, AEFIs & SAEs) reports.

2.2.1 Vaccines Vigilance

The successful deployment of the AEFI VigiMobile and VigiFlow applications countrywide resulted in a 1657% increase in the number of AEFI reports received in 2023 (total of 464 AEFI reports) compared to

2022 (total of 28 AEFI reports). Of the 464 AEFI reports received in 2023, 75 reports (16%) were serious and 389 (84%) were non-serious.

Overview of ICSRs received



Graph xx: Number of ICSRs received

The majority of the 464 reports were associated with the measles vaccine and dermatological reactions and fever were the commonly reported adverse events. Causality assessment, which is an evaluation of the likelihood that a particular treatment is the cause of an observed adverse event, was done for all the reports and 70% of the 464 AEFI reports were classified as related to the vaccine product, 12% were unclassifiable since adequate information was not available, 13% had a consistent temporal relationship but there was insufficient evidence for vaccine causing the event, 4% were immunization error related and 1% were coincidental, there were other underlying conditions.

2.2.2 Medicines Vigilance

As shown in the graph above there was a slight increase in the number of ADR reports received. A total of 235 ADR reports were received in 2023 as compared to 202 in 2022.

138 (59%) of the 235 ADR reports were associated with ARV medicines. Renal impairment was the commonly reported ADR due to tenofovir followed by weight gain due to dolutegravir. 53 (23%) of the 235 ADR reports were associated with Anti TB medicines. Isoniazid was the most reported medicine and dermatological adverse reactions were the most reported.

18% of the 235 reports were associated with other medicines. 85% of the 235 ADR reports were classified as either probable or possible after causality assessment. This means that the reactions in these reports were likely to have been attributed to the suspected medicines.

All the ICSRs received and processed were uploaded to the WHO VigiBase database. Feedback letters were sent to the reporters for all the ADRs.

2.3. Signal Detection

A safety signal is information on a new or known adverse event that is potentially caused by a medicine and warrants further investigation. Signals are generated from several sources, such as spontaneous reports of suspected adverse reactions, clinical studies, and the scientific literature. The evaluation of a safety signal is a routine pharmacovigilance activity to establish whether there is a causal relationship between a medicine and a reported adverse event. In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary.

2.3.1 Signal Detection by MAHs and Regulatory Decisions Taken



Graph xx: Signal detection by MAHs and regulatory decisions taken

A total of eighteen (18) potential signals were reviewed and assessed. One (1) signal assessment for pholcodine led to the withdrawal of a product from the market, two (2) signals for ritonavir and everolimus led to the updating of product information, one (1) signal assessment for pseudoephedrine was still ongoing however fourteen (14) signal assessments for different products APIs were closed since no additional pharmacovigilance activities were recommended as the benefits far outweighed the risk.

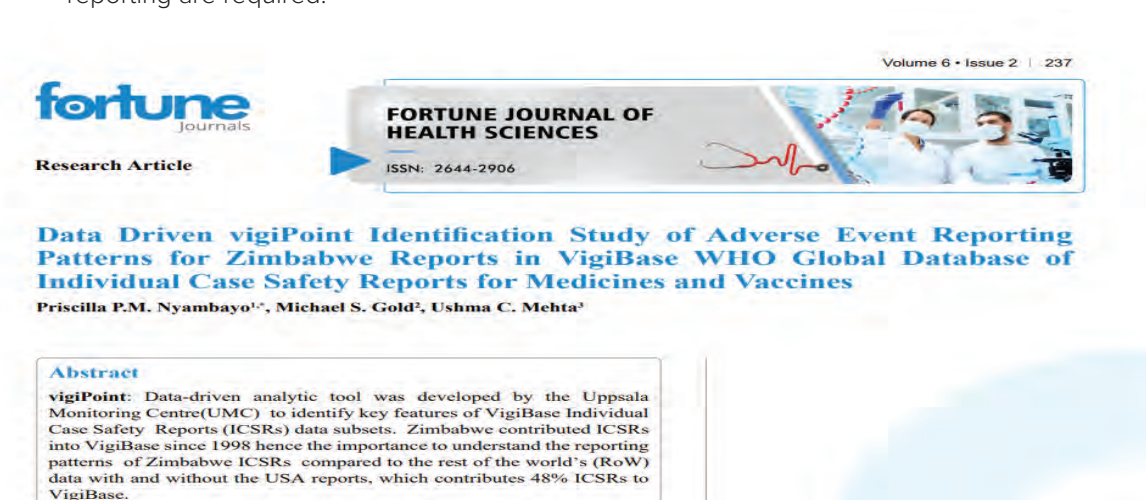
2.3.2 Signal detection using data-driven VigiPoint disproportionate analysis study and manuscript publication of the Zimbabwe ICSRs in comparison with Rest of the World (RoW) reports with or without USA reports.

A study was done using VigiPoint, which is a data-driven analytic tool developed by the Uppsala Monitoring Centre (UMC) to identify key features of VigiBase Individual Case Safety Reports (ICSRs) data subsets. Zimbabwe contributed ICSRs into VigiBase since 1998 hence the importance of understanding the reporting patterns of Zimbabwe ICSRs compared to the rest of the world's (RoW) data with and without the USA reports, which contributes 48% of ICSRs to VigiBase. The study explored VigiPoint differences in the Zimbabwe medicines and vaccines ICSRs reporting patterns compared to the RoW with and without the USA reports.

The study used VigiPoint analysis for VigiBase ICSRs reports analysis to outline data subsets of interest, pinpointing outstanding key features, using odds ratios subjected to statistical shrinkage distinguishing one data subset from another. The VigiPoint methodology compared 5213 Zimbabwe ICSRs reports in VigiBase from 1998-2022 with RoW with and without the USA unduplicated reports. To highlight features that deviate from the expected only, the threshold for the credibility interval of the log odds ratio was set at 0.5 and -0.5, respectively. The shrinkage was set to the VigiPoint default corresponding at 40% of the size of the Zimbabwe unduplicated ICSRs data subset.

A total of 5213 ICSRs (20% vaccines AEFIs, and 80% medicines AEs) were analysed using VigiPoint method. Zimbabwe ICSRs compared with RoW and without USA ICSRs reports had most reports submitted from nurses, AEs for people age ranges 18-44 years (43.1 vs 30.7%), infants and children 1-23 months (13.8 vs 3.0%) and children 2-11 years (12.1 vs 4.0%). Zimbabwe ICSRs were serious 71.6% vs 35.8% RoW mostly suspected antiretrovirals, antituberculosis medicines, or vaccines.

Study findings were characteristic of limited healthcare settings, like other studies that found low physician-patient ratios and higher rates of HIV, TB, and comorbid diseases. Further studies of Zimbabwe ICSRs causality assessment outcomes including the use of mHealth to enhance consumers/HCWs reporting are required.



Nyambayo, Priscilla & Gold, Michael & Mehta, Ushma. (2023). Data-Driven vigiPoint Identification Study of Adverse Event Reporting Patterns for Zimbabwe Reports in VigiBase WHO Global Database of Individual Case Safety Reports for Medicines and Vaccines. Fortune Journal of Health Sciences. 06. 10.26502/fjhs.121.

The publication is accessible on the following link;

<https://www.fortunejournals.com/fortune-journal-of-health-sciences-inpress-jht.php>

2.4 Post-registration Safety Reports:

Post registration applications such as safety variations, Periodic Safety Update Reports/ Periodic Benefit Risk Evaluation Reports (PSUR/PBRER), Risk management plans, recategorizations, and promotional materials were received by the Authority and processed as shown in the table below. All the post-registration reports which were received were processed within timelines.

Table x: Post-registration Submissions Received by the PVCT Division in 2023

Category	Applications received in 2022	Applications received in 2023	Applications processed in 2023	Timeline for processing	Actual time taken
Package insert updates	80	58	58	2 months	2 months
Additional Indication	1	4	4	2 months	2 months
PSUR/PBRER	8	17	17	2 months	2 months
Risk Management Plans	0	2	2	2 months	2 months
Safety communication	0	4	4	2 months	2 months
Promotional materials	32	49	49	2 months	2 months
Recategorizations	2	0	0	2 months	N/A

2.5 Pharmaceutical Industry Vigilance

The Authority requires all MAHs to have a functional pharmacovigilance system in place in line with the MCAZ Circular 3 of 2022 and the Pharmacovigilance Guideline for Pharmaceutical Industry (MCAZ PVCT GL02 Rev 1_February 2022). Circular 13 of 2022 provided a deadline that applicants were required to notify MCAZ in writing of their responsible person for pharmacovigilance or QPPV. The MCAZ PVCT Division conducted several virtual trainings of good vigilance practice (GVP), QPPV and GVP inspections in 2022. As a result, there was an increase in the number of submitted QPPV notifications. Follow-up was made to all the market authorisation holders (MAHs) who had not notified the Authority of their QPPV and most of them responded. Majority of the MAHs (99%) submitted their QPPV nominations and of the remaining 1%, two (2) MAHs had not yet responded and two (2) had requested for a deadline extension.

Table x: QPPV Notifications from the 99% MAHs Who Indicated Compliance with QPPV and GVP Guide Requirements.

	Number of MAHs	Number of MAHs who submitted QPPV notification	Number of MAHs who did not submit QPPV notification
Local	30	30	0
Foreign	248	244	4

2.6 Vigilance Projects including benefit/risk publications.

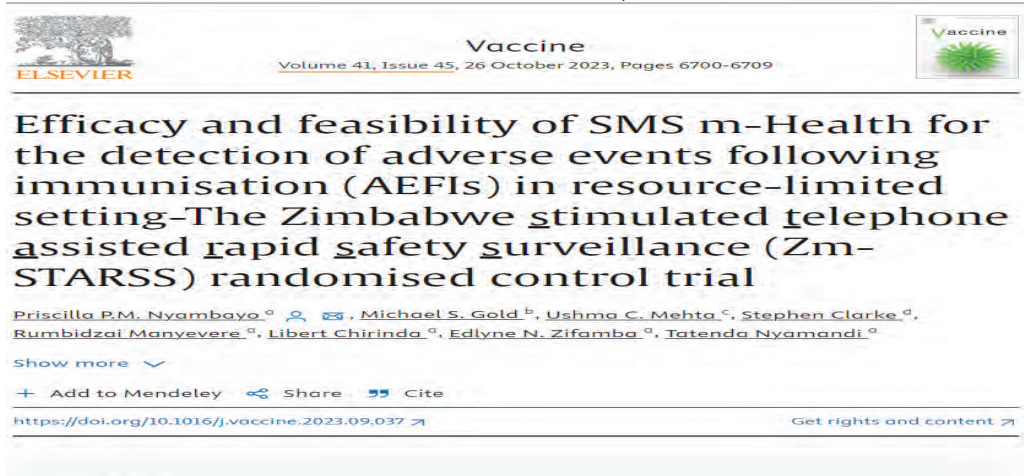
2.6.1 Strengthening pharmacovigilance and regulatory capacities in four Southern African countries (SPaRCS project).

The project was funded by the European and Developing Countries Clinical Trials Partnership (EDCTP). The aim of the SPaRCS project was to strengthen pharmacovigilance systems and clinical trials oversight of National Regulatory Authorities (NRAs) in Namibia, South Africa, Eswatini and Zimbabwe. The project used a participatory action learning, and co-creation approach to develop personal and institutional capacities of the NRAs in the four countries. A pharmacovigilance workshop and mutual learning site visit was held in July 2023 in Namibia. The project close-out meeting was held in Cape Town from 23rd – 24th October, 2023 and the main objective of the meeting was to reflect on the experiences of mutual learning within the SPaRCS project. The project successfully officially ended on 31st October, 2023 with recommendations for application for SPaRCS II funding and publication of the lessons learnt.



2.6.2 Active surveillance project of vaccines safety monitoring titled “The use of e-health to improve post-marketing surveillance of vaccines in Zimbabwe. A case study of Stimulated Telephone Assisted Rapid Safety Surveillance (Zm-STARSS) randomized trial assessing Adverse Events Following Immunization (AEFIs). Version 5.0 dated February 2021. (Zm-STARSS project).”

In a bid to strengthen pharmacovigilance in Zimbabwe using novel methods of e-health, MCAZ conducted a study with the above-mentioned title. The main purpose of the study was to explore an mHealth new way to collect information about adverse events that sometimes occur after vaccination. This mHealth new way made use of SMS and cell phone calls to communicate with the participants’ guardians and/ or adult Covid-19 vaccine recipients. The primary aim of the study was to determine if Zm-STARSS is more effective in detecting an AEFI than the usual standard of practice of passive reporting of AEFIs. The study had two arms, the passive arm and the CATI (Computer-assisted telephone interview) arm. The passive arm acted as the control arm and this group had individuals who reported AEFIs without being followed up. The CATI arm had individuals who were followed up with text messages on whether AEFIs occurred. A survey would also be carried out at the end of four (4) weeks using a phone call to the participants who were in the CATI arm. The study sites were Chitungwiza Central Hospital and Citimed Private Hospital. Site activation was done on the 6th of November, 2020 for Chitungwiza Central Hospital and on the 7th of November, 2020 for Citimed Private Hospital. A total of 4,560 participants including children and/ or adult/healthcare worker vaccine recipients were recruited. The study reached the target enrolment on the 24th of May, 2021 and enrolment was stopped. By the end of 2022 data cleaning and analysis was being done for the data collected and the study concluded that SMS-based AEFI surveillance can improve AEFI detection in an LMIC setting and should be considered as an approach to augment passive surveillance in these settings for both Covid-19 vaccines and childhood vaccines. A publication for the study was done in 2023 and the publication can be downloaded from the following link; <https://www.sciencedirect.com/science/article/abs/pii/S0264410X23011076?via%3DiHub>



2.7 Benefit /Risk Communication Medicines Information Bulletins and Publications.

To disseminate medicine information, the PVCT division managed to publish two (2) editions of the Medicine Information Bulletin in 2023. The bulletins were distributed through various channels to all the relevant stakeholders and electronic versions are available on the MCAZ website. The bulletins are accessible through the following hyperlinks;

<https://www.mcaz.co.zw/wp-content/uploads/2023/05/April-2023-Medicine-Information-Bulletin.pdf>
<https://www.mcaz.co.zw/wp-content/uploads/2023/09/August-2023-Medicines-Information-Bulletin.pdf>

The bulletins covered the following topics;

1. Pharmacovigilance updates
2. Submitting complete AEFI reports to the MCAZ using VigiMobile and VigiFlow for AEFI
3. Pharmacovigilance Regulatory safety updates
4. Long-term treatment with metformin and the potential for reduced vitamin B12 levels
5. Substandard and Falsified Medicines Alerts
6. Product recalls
7. Regional collaboration in pharmacovigilance
8. Pharmacovigilance trainings
9. Toxic epidermal Necrosis (TEN) associated with Sulphadoxine and Pyrimethamine tablets
10. Safety communication: Pholcodine-containing products; Azithromycin and the risk of potentially fatal heart rhythms
11. Approved Change of Category for distribution of registered medicines from 2010 to date
12. Medicine Safety Alert: Use of Cough and Cold Medicines in Children under the age of two years
13. Dangers of buying medical products from unauthorized sources
14. E-cigarette or Vaping Product Use-associated Lung Injury (EVALI)-Perspectives of a toxicologist
15. Risk Minimisation Measures for MabThera® and Hemlibra®
16. Unsafe Use of Glutathione and Injectable Vitamins as Skin-Lightening Agents

The following journal articles were published in 2023

- i. Nyambayo PPM, Gold MS, Mehta UC, Clarke S, Manyevere R, Chirinda L, Zifamba EN, Nyamandi T. Efficacy and feasibility of SMS m-Health for the detection of adverse events following immunisation (AEFIs) in resource-limited setting-The Zimbabwe stimulated telephone assisted rapid safety surveillance (Zm-STARSS) randomised control trial. *Vaccine*. 2023 Oct 26;41(45):6700-6709. doi: 10.1016/j.vaccine.2023.09.037. Epub 2023 Oct 5. PMID: 37805357. <https://www.tridhascholars.org/pdfs/scoping-literature-review-study-of-short-message-services-and-mobile-app-based-technology-as-an-mhealth-tool-for-active-participant-centered-adverse-events-following-immunisations-surveillance-using-a-low-middle-income-country-lens-JOCCR-S16-1086.pdf>
- ii. Nyambayo, Priscilla & Gold, Michael & Mehta, Ushma. (2023). Scoping Literature Review Study of Short Message Services (SMS) and Mobile App-Based Technology as an mHealth tool for Active Participant Centered (MAPC) Adverse Events Following Immunisations (AEFIs) Surveillance using a Low Middle-Income Country (LMIC) lens. *Journal of Clinical Cases and Reports*. 6. 308-327. 10.46619/joccr.2023.6-S16-1086. <https://www.sciencedirect.com/science/article/abs/pii/S0264410X23011076?via%3DiHub>
- iii. Priscilla P.M. Nyambayo, Michael S. Gold, Ushma C. Mehta. Data-Driven vigiPoint identification study of Zimbabwe ICSRs compared with RoW VigiBase data with and without USA reports. *Fortune Journal of Health Sciences*. 6 (2023): 237-245. <https://www.fortunejournals.com/fortune-journal-of-health-sciences-inpress-jht.php>

2.8 Haemovigilance

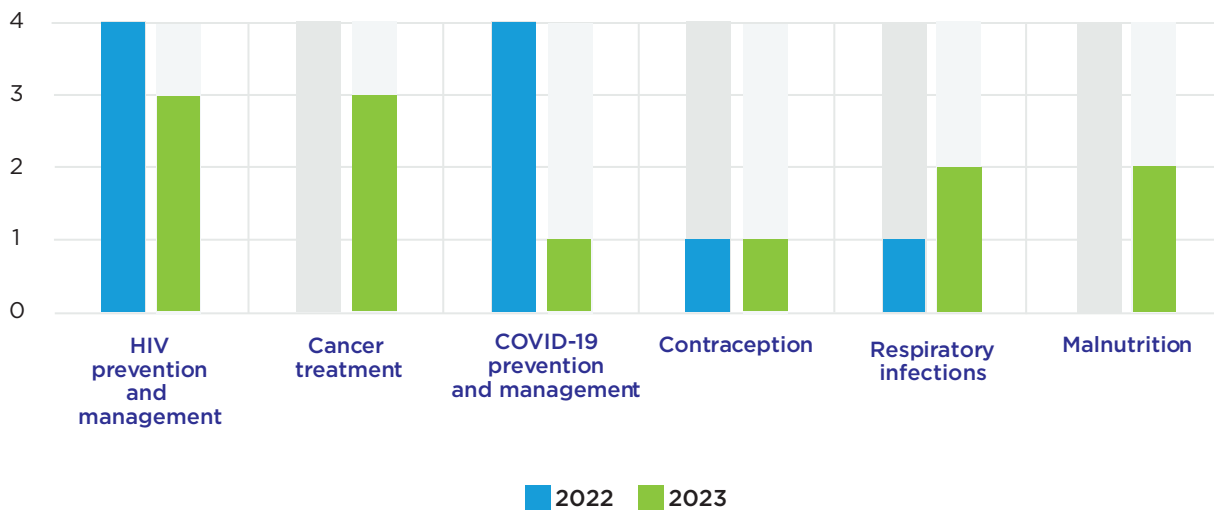
Haemovigilance is defined by the International Haemovigilance Network as a set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, through to their provision and transfusion to patients, including their follow-up. It includes the monitoring, reporting, investigation, and analysis of adverse events related to the donation, processing, and transfusion of blood, and taking action to prevent their occurrence or recurrence. The Authority with support from the Paul-Ehrlich-Institut Blood Train Next Generation team conducted a comprehensive self-assessment of blood regulation using the expanded WHO Global Benchmarking Tool for Blood from the 4th – 8th of December 2023. The assessment provided an overview of the

strengths and weaknesses of the national blood regulatory system to ultimately address identified gaps in a systematic way.



2.9 Clinical Trials Regulation Oversight.

New Clinical Trial Applications



Graph xx: Distribution of new clinical trial applications

Thirteen (13) clinical trial applications were received in 2023, a 30% increase from ten (10) new clinical trial applications received in 2022. All the clinical trials received in 2023 were submitted and processed using the electronic Clinical Trials Application and Registry (e-CTR) system. Of the thirteen (13) clinical trials received in 2023, three (3) were for HIV prevention and management, three (3) were for cancer treatment, one (1) was for Covid-19 prevention and management, one (1) was for contraception, two (2) were for respiratory infections and two (2) applications were for malnutrition. All the applications received were processed within the target timelines of sixty (60) working days.

Five (5) Good Clinical Practice (GCP) inspections were conducted in 2023 and all of them were routine inspections. Four (4) clinical trials were found to be operating at a satisfactory level of GCP compliance and one (1) clinical was not operating at an acceptable standard of GCP and consequently, enrolment was paused.

One hundred and ninety-five (195) Individual Case Safety Reports (ICSRs) were received from various authorized clinical trials in 2023 compared to one hundred and fifty-eight (158) in 2022, and these accounted for 21% of all ICSRs received by the MCAZ in 2023. Causality assessment of all the reports was conducted by the PVCT Committee and safety of the participant was satisfactorily managed by the researchers.

A total of US\$38 110 was generated from clinical trials activities against an annual target of US\$30 000 and is a 25% increase compared to the US\$30 344.35 received in 2022. The table below shows various clinical trial monitoring reports which were received and processed in 2023.

Table X: Clinical trials monitoring submissions processed from 1st January to 31st December, 2023..

Type of report	Number of reports received	Number of reports processed
Clinical trial protocol amendments	29	29
Progress, final and DSMB reports	89	89
Applications for the importation of investigational products	69	69
Protocol deviation reports	67	67
Total reports	254	254

There was a 25% decrease in the total number of clinical trial monitoring reports received in 2023 compared to 2022. There was however a 7% increase in the number of progress, final and DSMB reports received in 2023 compared to 2022. All reports were processed within timelines.

2.10 Clinical Trails and Pharmacovigilance Regulatory Centre of Regulatory Excellence (RCORE) Trainings.

The MCAZ was designated by the New Partnership for African Development (NEPAD) and the African Regulatory Harmonization (AMRH) as a Regional Centre of Regulatory Excellence (RCORE) in Clinical Trials. As a result, the MCAZ through the Pharmacovigilance and Clinical Trials Division designed an intensive course to build capacity and equip regulators in clinical trials and pharmacovigilance. In 2023, the division managed to conduct two (2) RCORE trainings highlighted in the table below:

Table X: RCORE Trainings Conducted In 2023

Country	Institution(s) Trained	Name of Course	Training Dates
Mauritius	National Pharmacovigilance Unit - Ministry of Health and Wellness	Pharmacovigilance training was conducted from 20-31 March in Mauritius	March 2023
Botswana, Eswatini, Lesotho and Mozambique	Botswana, Eswatini, Lesotho and Mozambique National Regulatory Authorities	SEARCH II project	11 th -15 th September 2023
Uganda	National Drug Regulatory Agency Uganda and National Ethics Committees	Statistical evaluation of clinical trial protocol applications using the AVAREF templates.	26 th – 27 th September, 2023

2.11 Annual Retention of Registered Medicines

In line with Section 35 Subsection (5) and Section 36 of the Medicines and Allied Substances Control (General) Regulations (1991), to maintain a human or veterinary medicinal product on the register of approved medicines, payment of an annual retention fee is required. If the retention fees for the product are not paid, the registration of the product would be cancelled and gazetted as such. Notification in writing is required if a medicinal product is no longer to be distributed and the registration of the product will be cancelled. The table below shows the funds which were collected for retention fees in 2023.

Table X: Annual Retention Fees Collected for The Year 2023

Income line	Expected Annual Target	Amount Received	Percentage of the Annual Target
Retention fees – Allopathic foreign medicines	US\$1,001,650.00	US\$1,010,194.50	93.5%
Retention fees – Allopathic local medicines	US\$158,125.00	US\$139,830.00	88%
*Retention fees – Complementary foreign medicines	US\$52 440.00	US\$22 424.00	42.7%
*Retention fees – Complementary local medicines	US\$690	US\$115	17%

***The year for complementary medicines retention fees runs from July to June.**

There was a 0.5% increase in the retention fees collected for allopathic foreign medicine compared to 2022. There was a 12% decrease in the retention fees collected for allopathic local medicines. One (1) applicant had not yet paid their retention fees and had submitted a payment plan to the Authority.

3. Capacity Development Issues Undertaken.

The Authority continues its quest to be equipped with adequate human resources who are competent and adequately trained. The following trainings shown in the table below were undertaken by the PVCT staff in 2023 in line with the training plan to develop their capacity. All the trainings were conducted virtually.

Table X: PVCT Staff Trainings Conducted In 2023

	Program/Course	Offered by	Date	Venue	Number of officers trained
1.	Clinical assessors' course 2023	University of The Witwatersrand, Pharmacometrics Africa	Oct 2023	Online	1
2.	PEI_PV training workshop	Paul- Ehrlich- Institut GHP Programme	29/03/2023 to 31/03/2023	Online	9
3.	WHO cGMP training on vaccine manufacturing	WHO	08/09/2023 to 10/10/2023	Online	8
4.	PMDA course on Multi-Regional Clinical Trial (MRCT)	PMDA - Japan	05/10/2023	Online	1

5.	PMDA course on pharmacovigilance	PMDA – Japan	28/09/2023	Online	1
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4. Key/Notable Achievements

- 3.1 In 2023, the Pharmacovigilance and Clinical Trials scored the following achievements: The division attained WHO GBT maturity level 3 for the vigilance and clinical trials functions.
- 3.2 Successful deployment of the AEFI VigiMobile and VigiFlow for AEFI reporting applications which led to an increase in the number of AEFI reports received and improved reporting timelines.
- 3.3 The division published two (2) Medicines Information bulletins and three (3) journal articles.
- 3.4 Some members of the division presented on pharmacovigilance at various forums which included the PV AfriSummit Workshop, and the Joint CPCPZ – PSZ Annual Congress.

4 Lessons Learnt and Challenges

Lessons Learnt

- 4.1 There is a need to continue increasing automation of all the key division processes as automation has proved to increase the efficiency of processes.
- 4.2 The number and quality of ICSRs submitted to MCAZ tend to increase when pharmacovigilance trainings are conducted.

Challenges

- 4.3 The uptake of the ADR electronic reporting tools was low in some areas due to internet challenges and there was a decreased rate of ADR reporting from ART and TB medicines.

6. Plans for the Future (2024)

- 6.1 MCAZ-PEI Vacc Train workshop to build capacity for the officers in clinical trials regulation and pharmacovigilance in 2024.
- 6.2 Collaboration with other regional regulatory authorities for clinical trials and pharmacovigilance activities.
- 6.3 Increase the number of good vigilance practices (GVP) inspections for Market Authorisation Holders to ensure compliance of the marketing authorization holder pharmacovigilance system with the MCAZ legislation and guidelines.
- 6.4 ADR VigiMobile application to be deployed in 2024 when developed since it is expected to be more user-friendly than the deployed AEFI VigiMobile application that is less internet dependent.

▶ Chemistry Division

Introduction

The Medicines Control Authority of Zimbabwe Chemistry Laboratory is a National Quality Control Laboratory (NQCL) whose mandate is to test medicines which are manufactured in Zimbabwe as well as products that are imported and consumed by the Zimbabwean public. The purpose of testing is to check the quality attributes of medical products so that safe, effective and good-quality medicines are available on the Zimbabwean market. This is done in collaboration with the Ministry of Health and Child Care (MoHCC), the World Health Organisation (WHO) and the African Medicines Quality Forum (AMQF). Funding from development partners such as The Global Fund to fight HIV/AIDS, Tuberculosis and Malaria, United Nations Development Programme (UNDP) and others greatly assists the laboratory with resources used by the laboratory. The Global Fund through UNDP has a long-term agreement (LTA) with The Medicines Control Authority of Zimbabwe in quality control testing of medicines in Zimbabwe and other countries. The Chemistry Laboratory is World Health Organization (WHO) Prequalified and ISO 17025 Accredited, which means that it can conduct robust testing of medicines following world-class standards.

Activities

The areas of regulatory involvement in the National Quality Assurance Control Programme include the following:

- i. Pre-distribution analysis of medicines to ensure that good quality and safe products are available in the medicines distribution channel down to the rural health centres.
- ii. Post-market surveillance in monitoring for product defects, falsified and sub-standard medicines.
- iii. Adverse events monitoring and investigative testing in collaboration with the Pharmacovigilance and Clinical Trials (PVCT) Division.
- iv. Where pre-registration testing is necessary the laboratory performs chemical testing to assess the quality of the medicines before they are allowed onto the Zimbabwean market.
- v. Training in analysis of medicines.

The main objective of the Chemistry laboratory's activities is to protect human and animal health from consuming poor-quality medicines which may contribute to health challenges such as general anti-microbial resistance and resistance specifically to life-saving essential medicines including anti-retroviral, anti-TB and anti-malarial medicines.

Samples analysed by the chemistry laboratory 2022 vs 2023

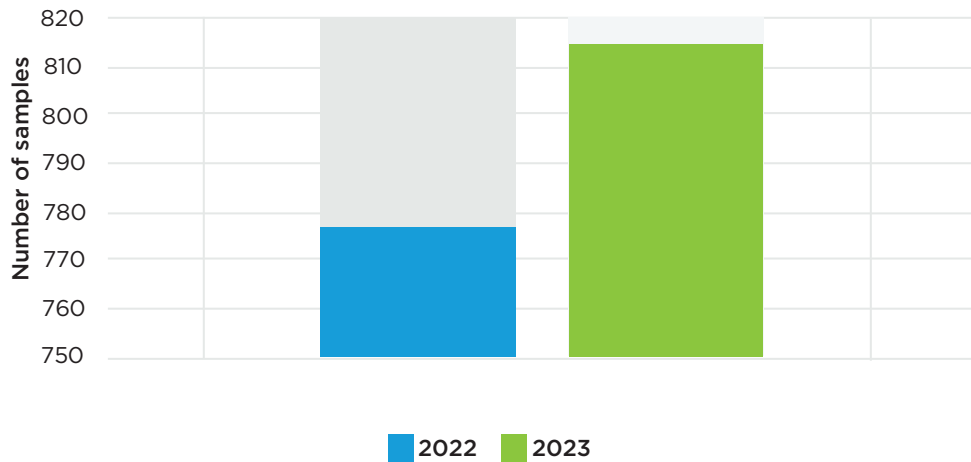


Figure 1: A comparison of samples analysed by the Chemistry Laboratory 2022 – 2023

It is important to follow up on medicines available on the market to combat counterfeits and substandard medicines. During the year 2023, eight hundred and fifteen (815) samples were analyzed by the Chemistry Laboratory as shown in **Figure 1**. The samples analysed included medicines collected as post market surveillance in the pharmaceutical distribution channel in Zimbabwe and from other countries. The MCAZ partners played a major role in facilitating the post market surveillance activities in Zimbabwe as a way of confirming the quality, safety and efficacy of the medicines in the market.

Analytical techniques used to analyse the samples in the laboratory included chromatography, FTIR and UV-Vis spectrophotometry. Physical tests performed on the samples against specifications included Dissolution (tablets/capsules/suspensions), Disintegration (tablets/capsules), Friability (tablets), Hardness (Tablets) and Uniformity of Weight for the dosage units.

Zimbabwe Post-Market Surveillance

The samples analysed for local post-market surveillance in Zimbabwe in 2023 were classified as either anti-malarial, anti-tuberculosis, antiretrovirals or other essential medicines with anti-tuberculosis and antiretrovirals making up 68% of the medicines analysed. The distribution of samples analysed in 2023 is illustrated in **Figure 2**.

Local Post Market Surveillance Samples Analysed in 2023

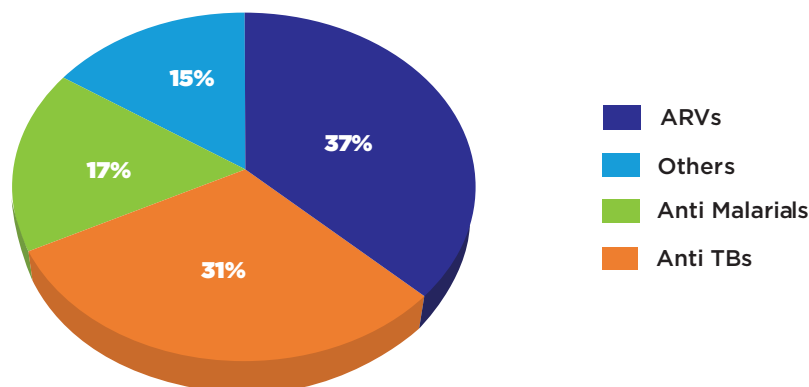


Figure 2: Distribution of analysed samples by classification

The “Others” segment included a variety of medicines including antibiotics, antidiabetics and antihypertensives.

External Customers

In 2023, the Chemistry Laboratory analysed samples brought under UNDP Global Fund Long Term Agreement (LTA) from countries such as Burundi, Chad, Congo Brazzaville, Djibouti, Guinea Bissau, South Sudan and Sudan. In addition, the laboratory tested samples received from CORDAID Democratic Republic of Congo (DRC), National Aids Secretariat Gambia, Madagascar and Zambia. The volume of external samples received in 2023 increased with the laboratory receiving samples from new customers such as Botswana Medicines Regulatory Authority (BOMRA), Central Purchasing Centre for Essential Medicines and Materials Djibouti, The Medicines and Health Technologies Agency, (ARMED) Angola, National Medicines and Food Administration, Eritrea and Burundi Food and Medicines Regulatory Authority (ABREMA). The number of samples received and analysed from each customer is shown in **Figure 3**.

External Samples analysed per customer

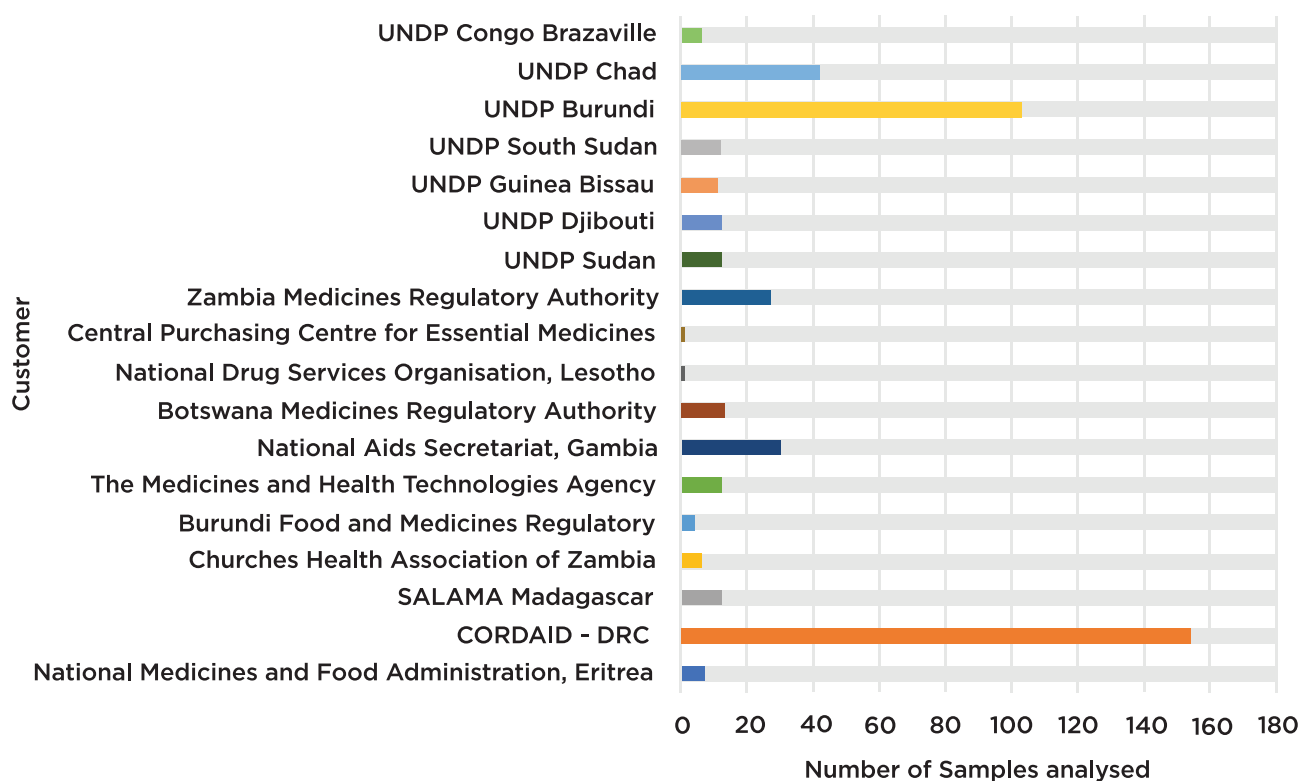


Figure 3: Samples analysed for customers outside Zimbabwe in 2023

Cannabis Testing

With the successful completion of the Cannabis laboratory set-up, testing commenced in 2023. Samples submitted for analysis were in different forms such as flowers (41%), oils (32%), powders (18%), semi-solid (5%) and biomass (4%). More samples are expected to be tested in the coming years owing to more equipment being installed and calibrated. The distribution of the samples tested is illustrated in **Figure 4** below:

Cannabis Samples Tested in 2023

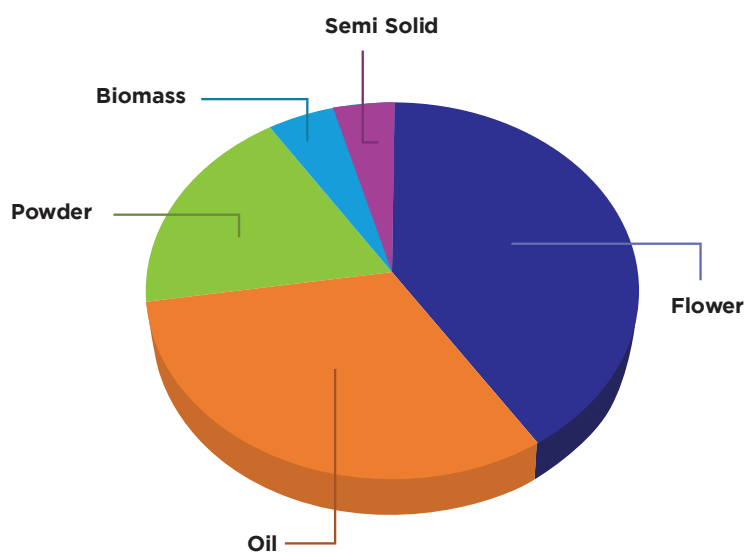


Figure 4: Cannabis samples analysed in 2023

Inter-Laboratory Proficiency Testing

The Chemistry laboratory participated in eight (8) inter-laboratory proficiency testing schemes in 2023. More proficiency test providers advertised testing schemes as compared to 2022 due to the lifting of restrictions after Covid-19 pandemic. These were coordinated by USP Proficiency Testing Program (PH-PTX80) and the African Medicines Quality Forum (AMQF) coordinated by USP Ghana. Tests covered a variety of techniques provided by the laboratory, such as Related Substances by HPLC, Dissolution by HPLC, Identification by UV-Vis and FTIR, Disintegration, pH, Conductivity, and Uniformity of Dosage by HPLC. **Figure 5** illustrates proficiency testing schemes participated by the Chemistry laboratory in 2022 and 2023.

Inter-Laboratory Proficiency testing schemes (PT)

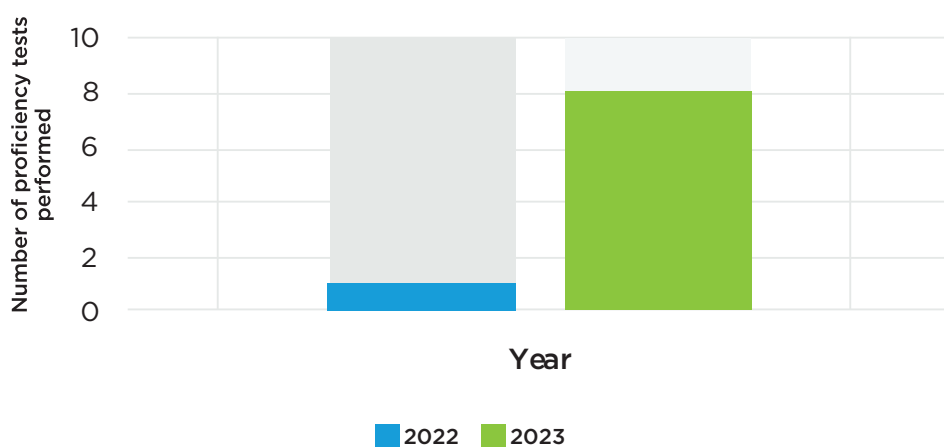


Figure 5: Samples Analysed In Proficiency Testing Schemes

Capacity Development Issues Undertaken.

The Cannabis laboratory was successfully set up and testing of samples commenced. Major equipment procured included High Performance Liquid Chromatography (HPLC), Liquid Chromatography Mass Spectrometry (LC-MS), Gas Chromatography-Mass Spectrometry (GC-MS) and Inductively Coupled Plasma Mass Spectrometry (ICP-MS).

Contamination of cough syrups was a topical issue in the year 2023 with some African countries reporting fatalities due to Diethylene Glycol (DEG)/Ethylene Glycol (EG) in children's formulated syrups. To protect public health, the Chemistry Laboratory responded by developing the capacity to test for Diethylene Glycol/Ethylene Glycol in liquid preparations using major equipment such as Gas Chromatography (GC) with Flame Ionisation Detector (FID).

Furthermore, the Chemistry laboratory hosted three Technicians from Autoridade Nacional Reguladora de Medicamento, IP (ANARME), which is the Mozambique national quality control laboratory. The Technicians were at MCAZ Chemistry laboratory for one (1) week on a hands-on HPLC analysis training of different dosage forms.

Key/Notable Achievements

In 2023, the Chemistry laboratory scored the following achievements:-

- i. On-site assessment by WHO Pre-qualification inspectors and recommended for maintaining WHO Pre-qualification status.
- ii. Retained ISO/IEC 17025 SADCAS accreditation for the HPLC and UV-Vis techniques.
- iii. Improved customer satisfaction due to reduced turnaround times leading to enhanced revenue streams for the Authority.
- iv. Retained existing external customers

and partnered with new ones.

- v. Lessons learnt from 2022 on delays at customs clearance led to improved communications with customers in 2023 on requirements to shorten the clearance process. As a result, sample clearance turnaround times at customs were reduced significantly.
- vi. The Cannabis laboratory was successfully set up and testing of samples commenced.

Challenges And Lessons Learnt

The Chemistry laboratory witnessed an increase in number of samples received for testing from customers outside Zimbabwe in 2023. Constant communication with our external customers and Zimbabwe customs officials turned out to be the key that resolved challenges faced in previous years related to delays in the clearance of samples by the customs department. In addition, customers were encouraged to ensure that all documentation that accompanied the samples was filled in correctly and the purpose of testing was clearly highlighted on the sample packages.

Plans For the Future.

The Chemistry Division intends to expand the scope of testing to include DEG/EG in liquid/oral preparations, cannabis-formulated products and complementary medicines using instrumentation available in the Cannabis laboratory including Liquid Chromatography Mass Spectrometry (LCMS), Gas Chromatography-Mass Spectrometry (GCMS) and Inductively Coupled Plasma (ICP).

Medical Devices Laboratory

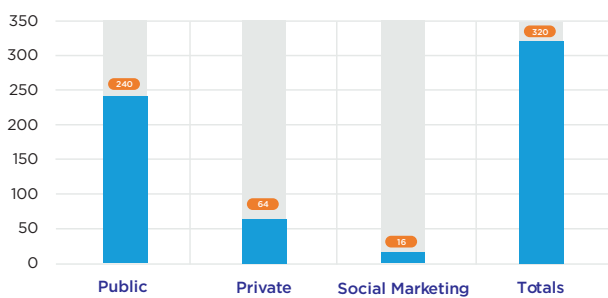
The Medical Devices laboratory conducts quality conformity assessment of condoms and medical gloves as guided by the MCAZ regulations and international standard requirements. The laboratory is ISO/IEC 17025 accredited for condom testing.

Major Highlights: 2023

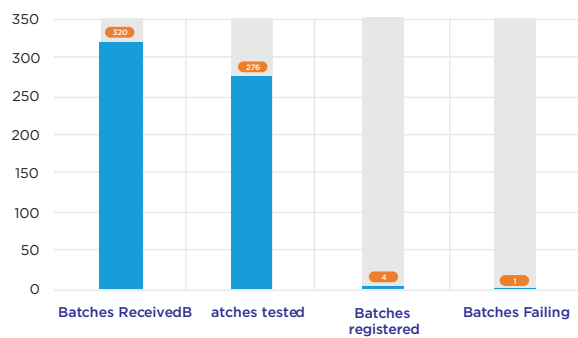
Condoms

Condoms received and tested in 2023

Condom batches submitted: Market segmentation



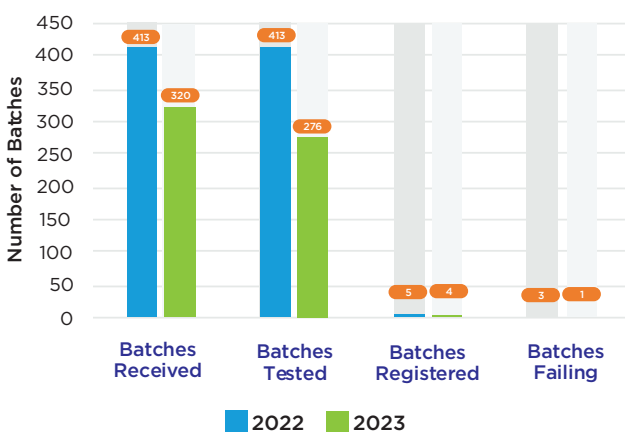
Condom testing analysis 2023



- The laboratory received three hundred and twenty (320) condom batches in 2023, two hundred and seventy-six (276) batches were tested in the year ending 2023.
- There was one (1) failed batch in the year and four (4) batches that were registered in the year.
- Condoms for the public sector (ZNFPCC) were 75% of the total condom batches submitted whilst, the private sector had 20% of condoms submitted for testing. Condoms submitted for by Social Marketing customers were 5% of the total submissions.

Comparison Between 2022 And 2023: Condoms

Condom testing Analysis 2022 vs 2023



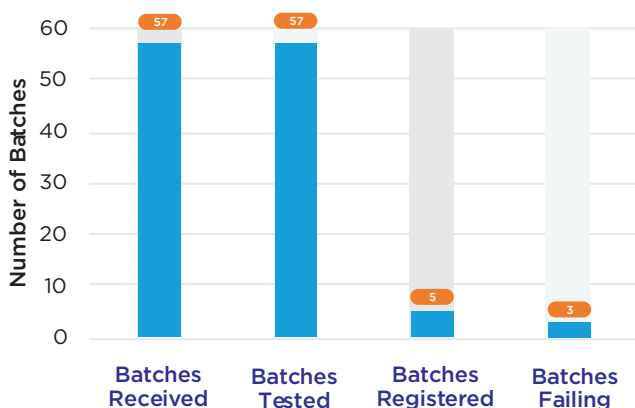
Condom batches submitted: Market segmentation 2022 vs 2023



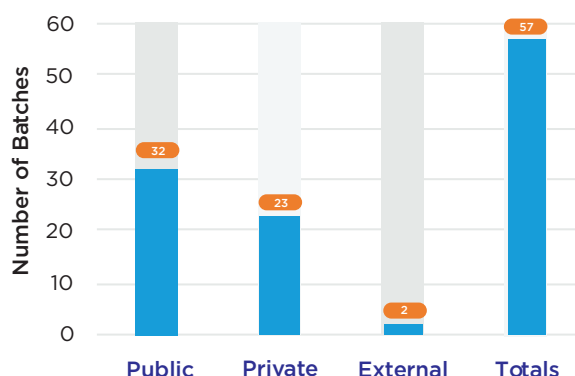
1. There was a 22% decline in the number of condom batches submitted for testing, the decline was due to a reduced number of batches submitted by the public sector and social marketing sector. There was a 16% increase in the number of condoms tested from the private sector.
2. The number of new registrations reduced in 2023 with four (4) new condom brands/type registered compared to five (5) in the previous year.
3. One condom batch failed in 2023 which was lower than the three (3) that failed in 2022

Gloves

Glove testing analysis 2023



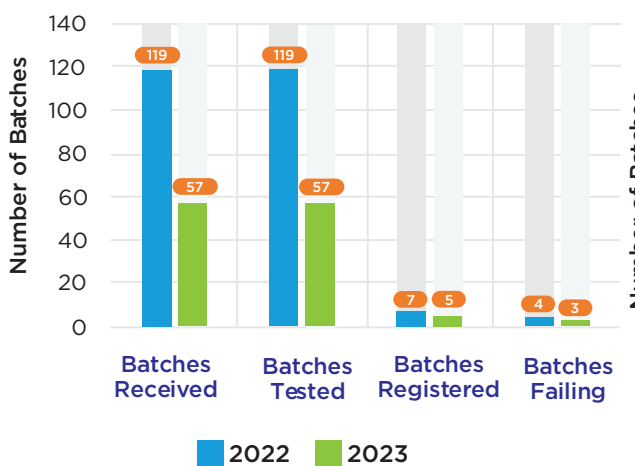
Glove batches submitted: Market segmentation



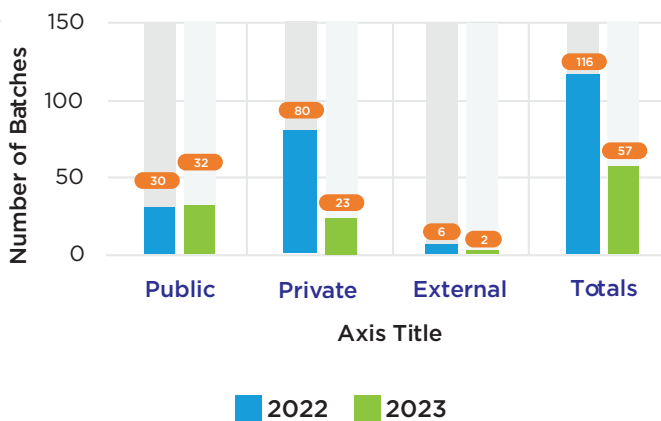
- a. The laboratory received and tested fifty-seven (57) glove batches for testing in year 2023.
- b. There were five (5) new registered glove brands.
- c. Three (3) glove batches failed quality conformity testing.
- d. Gloves tested for the public sector amounted to 57% of the total gloves submitted for testing with 40% being taken up by gloves that were for the private sector. The rest were batches received from regional customers.

Comparison between 2022 and 2023 : Gloves

Glove testing analysis 2022 vs 2023



Glovebatches submitted: Market segmentation 2022 vs 2023



- 1) There was a 48% decline in the number of glove batches submitted for testing, the decline was largely due to a reduced number of batches submitted by the private sector.

- 2) The number of gloves batches received from the public sector did not significantly change however, the batch sizes increased in size for each batch imported
- 3) The number of new registrations reduced in 2023 with five (5) new glove brands registered compared to seven (7) in the previous year.
- 4) Three (3) glove batches failed in 2023 compared to the four (4) that failed in 2022.

Quality Management Systems

- a) SADCAS conducted a surveillance audit in the year 2023, and the laboratory maintained its ISO 17025 accreditation status.
- b) The laboratory continued participation in annual proficiency testing schemes coordinated by the FHI360 (USA) and Enersol (Australia) for condom and glove testing and the results were satisfactory.
- c) The laboratory during the course of 2023, was recommended the continued facilitation of the AfroCondomNet Proficiency testing scheme for male condoms supported by the United Nations Population Fund (UNFPA).

Equipment

The laboratory received two (2) Enersol Visual Leaks testers for the testing of gloves and condoms as well as an automated glove width tester with the accompanying software.

Factory Audits

The following factories were inspected in year 2023 for compliance to the requirements of ISO 13485:2016 Medical Devices-Quality Management Systems (Requirements for Regulatory Purposes):

- A. Suretex Bangalore, India (Condoms) – Public Sector manufacturer
- B. Top Glove, Malaysia (Medical Gloves) - Public and Private Sector manufacturer
- C. Innolatrix (Thailand) Limited, Thailand (Condoms) - Public Sector manufacturer
- D. Karex Industries, Malaysia, (Condoms) - Public and Private Sector manufacturer

The premises complied with the current standard for ISO 13485:2016, Good Manufacturing Practices and Zimbabwean regulatory requirements. A continued supply of products on the Zimbabwean market was recommended.

Achievements

The laboratory managed to achieve most of its set goals as provided in year 2023 work plan. Most samples received were tested within set turnaround times, hence positively impacting on effective regulatory processes. The laboratory performed very well in all the Proficiency Testing schemes for condoms and gloves testing. There were no outlier results in the year 2023. The laboratory has continued to facilitate regional condom proficiency testing schemes in partnership with UNFPA. The laboratory continued collaboration with relevant stakeholders in supporting the development of new regulations for in-vitro diagnostics.

▶ Microbiology Laboratory

Introduction

The Microbiology Laboratory conducts microbiological testing of pharmaceutical preparations, allied substances and medicinal cannabis. The laboratory supports the MCAZ regulatory functions as indicated below:

- i. Pre-distribution analysis of medicines to ensure that good quality and safe products are circulated in the medicine’s distribution chain.
- ii. Supports Post Market Surveillance (PMS) through microbiological testing of PMS samples.
- iii. Adverse event monitoring in collaboration with the PVCT Division.
- iv. Where pre-registration testing is deemed necessary, the laboratory performs microbiological analysis to establish the quality of the medicines before they are allowed onto the Zimbabwe market.

Comparison of Samples Received and Tested In Microbiology Laboratory 2021-2023

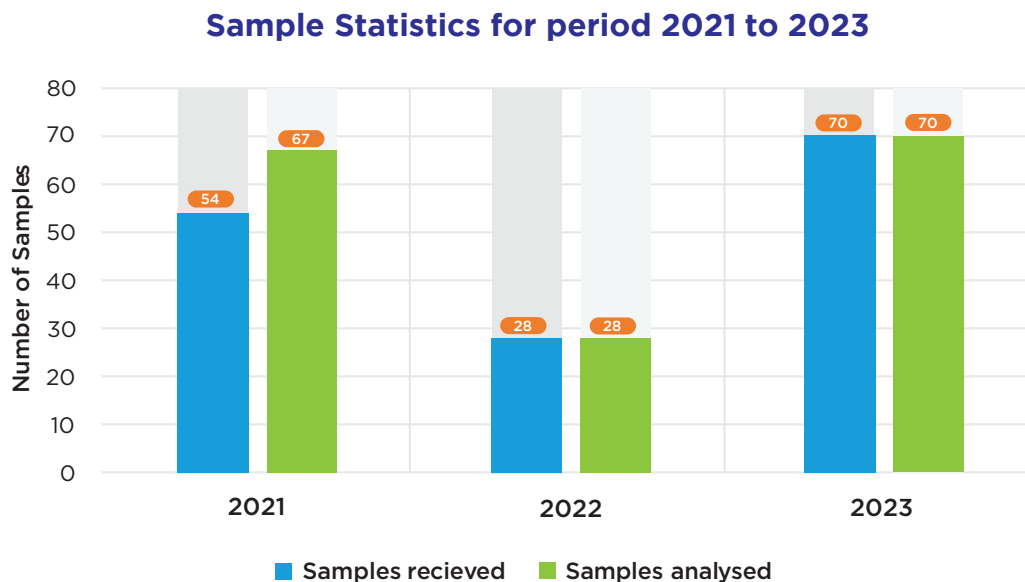


Figure 1: Trend Analysis of Samples received and tested by the Microbiology Laboratory (2021 to 2023)

1. During the year 2023, the laboratory received and tested seventy (70) samples.
2. The laboratory experienced a dip in the number of samples received for testing in the year 2022, however, there was an increase in the number of samples tested in 2023 compared to 2022.
3. The Microbiology Laboratory still receives a small number of samples for testing, which is an effect of the laboratory’s remodelling exercise which caused a four (4) year disruption in testing.

Achievements

- a. The laboratory continues to participate in Proficiency Testing Schemes such as the internationally renowned LGC Pharmassure PT Scheme. In the year 2023, the Laboratory had an outstanding performance for the Sterility and Microbiological Examination of Non-Sterile Products (MENSPP) tests for the LG Pharmassure PT Scheme. The laboratory managed to achieve an average turnaround time of 94.3% in year 2023 which impacted positively on the strategic goal of effective regulatory processes.
- b. In 2023, the Microbiology Laboratory attained ISO 17025 SADCAS accreditation where three (3) analysts were accorded SADCAS Technical Signatory status for three (3) microbiological tests namely: Sterility, Microbiological Examination of Non-Sterile Products and Microbial Identification by Vitek 2 Microbial Identification System.

Plans For the Future

The Microbiology Laboratory is working towards attainment of WHO Prequalification Status which will further enhance the reliability of test results generated by the laboratory and gaining international recognition.



▶ Quality Unit

Introduction

The Quality Unit in 2023 maintained its focus on a more efficient and effective work ethic, demonstrably adhering to Quality Management Systems (QMS) as evidenced by the maintenance and retention of key QMS accreditations and certifications. This focus aligns with the Authority's strategic goals for the successful execution of its Strategic Plan.

The Authority actively fosters strong ties with its regional stakeholders. This commitment was exemplified by two strategic interactions. First, the Quality Unit served as a gracious host to the Rwandan Food and Drug Administration (FDA) for a knowledge-sharing and training program focused on the best practices for implementing ISO 9001:2015. Second, the MCAZ's Quality Unit undertook an on-site audit of the Botswana Medicines Regulatory Authority (BOMRA) to assess their compliance with the same standard. These interactions underscore the MCAZ's unwavering dedication to fostering regional collaboration and building capacity within the regulatory framework.

Activities

A. Conducted internal audits and effectiveness checks of QMS standards, including ISO/IEC 17025:2017, ISO/IEC

9001:2015, World Health Organization Global Benchmarking Tool (WHO GBT), and WHO Prequalification requirements.

- B. The Sample Repository Office (SRO) achieved a significant 5.7% increase in sample processing in 2023, receiving 1810 samples compared to 1712 in 2022. This demonstrates the office's efficiency in managing sample intake. The SRO is committed to continuous improvement and investigating potential areas to optimize test result release times.
- C. Maintained a system for continuous monitoring of key process timelines for all MCAZ Units and Divisions to measure organizational performance.
- D. Consolidated, monitored, analysed, evaluated, and implemented the MCAZ Strategic Plan.

Focus on Notable Changes and Developments (Statistics)

In line with enhancing customer satisfaction, the Quality Unit presented a Customer Journey Mapping exercise to various stakeholders during the MCAZ Annual General Meeting (AGM). This initiative aimed to improve understanding of stakeholder experiences when interacting with the MCAZ.

Capacity Development Issues Undertaken.

Capacity Development	Officers Developed
Assisted WHO GBT self-benchmarking for Blood and Blood Products, resulting in draft guidelines currently under review	One

Key Achievements

1. Maintained SADCAS Accreditation in ISO/IEC 17025:2017, demonstrating an ongoing commitment to quality standards.
2. Secured the expansion of the MCAZ's SADCAS 17025:2017 accreditation scope to include the Microbiology Laboratory. This enhances service offerings and reinforces the MCAZ's position as a leading regulatory body with broader testing capabilities.
3. Retained Standards Association of Zimbabwe (SAZ) ISO 9001:2015 certification, underscoring the organization's focus on effective management practices.
4. Maintained the Chemistry Laboratory WHO Prequalification, a testament to the laboratory's expertise and adherence to rigorous quality standards.

Lessons Learnt and Challenges

While progress has been made with spreadsheet trackers complementing paper-based document control processes, a robust electronic document

management and control system is urgently needed. Implementing such a system should be a priority to optimize efficiency and truly mitigate the challenges associated with paper-based documents. This will significantly improve document control and contribute to the overall effectiveness of the Authority.

Plans For the Future

Building on a year of continuous improvement, the Quality Unit's focus in 2024 will be the active integration of WHO GBT functionalities into existing QMS standards. This strategic effort positions the MCAZ to achieve Maturity Level 3 (ML3) compliance throughout the year. Additionally, the Unit will pursue ML3 status in WHO GBT assessments and endeavour to secure WHO Prequalification for the Microbiology Laboratory. These achievements will elevate the MCAZ's recognition within the field, potentially generate new revenue streams, and ultimately pave the way for becoming a WHO Listed Authority. In parallel, the implementation of Office 365 is being explored as a potential solution to address the paper-based challenges currently hindering document control processes.



▶ Human Resources

Introduction

The year 2023 marked improvement in the Authority’s continual efforts towards employee engagement as the engagement index increased from 49% to 52%. The year was also the second witnessing the continued implementation of the Authority’s 5-year Strategic Plan (2022-26).

Capacity Development Issues Undertaken.

The learning and development thrust adopted by the Authority saw more than 200 various training programmes both in-house and external undertaken by employees across all departments. This was a huge investment in human capital aimed at improving both organizational and employee performance as well as productivity.

Key/Notable Achievements

Notable Achievements Included the Under-Listed:

1. Staff recognition and reward through staff advancements and promotions driven by competence-based assessment tools.
2. Significant reduction of the vacancy rate from 12% to 7% with key positions filled.
3. Accelerated learning and development efforts for employees through identified skills gaps and reasonable training budget allocation.
4. Introduction of new monetary and non-monetary benefits such as mortgage scheme, motor vehicle loan scheme, personal loan scheme, etc.

Lessons Learnt and Challenges

The most notable challenge was sustainable employee remuneration as several competitive employers continued to poach from the Authority’s skills base. This has become a perennial drawback in so far as employee retention strategies are concerned. However, the Authority would continue to address the issue of low remuneration by closing gaps where sustainable for both monetary and non-monetary benefits.

Plans For The Future.

Going forward, the Authority envisages being an attractive employer of choice through implementation of various sustainable programmes and projects that include talent management inclusive of career growth and succession planning, entrenched value-based culture programmes, and comparable remuneration structures among others.



► Public Relations

Medicines and allied substances regulation involves a range of stakeholders, from patients, healthcare professionals, academia, pharmaceutical companies, development partners, and the general public. They all rely on timely and trusted communication. Good communication and transparency go a long way to building trust and confidence in medicines regulation and public health. The Public Relations Office is responsible for shaping and maintaining the reputation, credibility, and public image of an organization. It is responsible for building and maintaining mutually beneficial relationships with key stakeholders.

Public awareness of the existence of and operations of the Medicines Control Authority of Zimbabwe is key in enhancing confidence and protecting the right of the public to quality safe and efficacious medicines and medical devices. To this end, the Authority's communication strategies sought to raise informational awareness on the extent to which the Authority safeguards the public's right to safe, efficacious, and good-quality medicines and medical devices.

Exhibitions

Events such as trade fairs, agricultural shows, road shows and consultative meetings provided the Authority with a platform to interact with the public and receive instant feedback. The Authority



exhibited at the Zimbabwe International Trade Fair (ZITF) and also conducted several consultative meetings. The Authority also sponsored a prize for the best stand (health) at the Harare Agriculture Show. Collaborative opportunities with other players in the industry, universities, and schools were also forged to maximize brand visibility at the lowest possible cost. The Authority got the opportunity to educate members of the public about the importance and the advantages of accessing registered medicines from licenced persons and premises. We got valuable feedback and the concerns of the public regarding the proliferation of medicines on the illicit market.

Media Relations

Partnerships with related stakeholders such as media practitioners provided the Authority with opportunities to increase brand visibility at a much lower cost. The Authority received positive coverage in the media, both in private and public media. This helps to raise awareness about the operations of the Authority. The Unit continued to monitor the media landscape for all positive and negative coverage through digital monitoring tools. The Authority enjoyed positive spin-offs from media coverage from various events attended as it trended both online and traditional media channels. This positive coverage helped the public to learn more about the Authority and how it works in protecting their health by making sure that they have access to medicines that are safe, effective, and of good quality. Collaboration and active engagements with media houses greatly assisted in ensuring the brand received positive and fair coverage. This went a long way in enhancing public confidence in the Authority and the country's medicines regulatory environment.

Digital Communications

The use of digital platforms such as social media,

websites, and online banners has dominated the Authority’s digital strategy. This was mainly due to the ability of these platforms to engage with all our stakeholders at a low cost and receive instant feedback. Our digital footprint continues to grow with customers utilizing such platforms for inquiries complaints and to seek assistance.

The growth in usage of social media platforms by the public provided the Authority with a cheaper alternative to drive visibility and information dissemination. The Authority’s website acts as the central repository of all up-to-date information and is accessible to all key stakeholders namely the public, pharmaceutical industry players, and the media. The website is consistently updated to ensure stakeholders have access to updated and relevant information. The Authority is active mainly on Facebook, X (formerly Twitter), Instagram, LinkedIn and WhatsApp.

Collaborations and Other Activities

The Authority also held quarterly industry liaison meetings to keep its stakeholders updated on the operations of the Authority, and new developments regarding medicines regulation.

The MCAZ believes in catching them young. To this end, the Authority employs a school outreach strategy that has proved effective. The Authority visited several schools to address learners, their educators, and in some instances, their parents on rational use of medicines and also Drug and Substance Abuse.

The Zimbabwe Pharmacy Students Association (ZIPSA), as one of the key stakeholders, has done several sessions with the MCAZ including the White Coat Day, and Annual Conference, among others.

Customer Satisfaction Survey

The Authority is committed to the delivery of quality service. As part of the continuous improvement process, a client satisfaction survey was commissioned through an independent research agency. The overall satisfaction index was at 71%. These results helped to reaffirm the Authority’s commitment to the delivery of quality service to its stakeholders.

4.0: Summary indicators				
STAKEHOLDER CATEGORY	CUSTOMER SATISFACTION INDEX (CSI)	COMPLAINTS RESOLUTION RATIO (CRR)	CUSTOMER EFFORT SCORE (CES)	NET PROMOTER SCORE (NPS)
Pharmacies (Retail, community or hospital)	72%	59%	74%	35
Dispensing medical practitioners	70%	56%	78%	35
Industrial clinics	74%	63%	83%	46
Veterinary Medical General Dealers	71%	56%	74%	36
Clinical trials researchers	60%	33%	63%	-35
Wholesalers	74%	57%	79%	54
Manufacturers	75%	80%	90%	59
Importers	69%	73%	75%	41
Overall	71%	56%	77%	34

The Authority’s omnichannel helpdesk solution provided a seamless customer experience and reduced resolution of customer queries and complaints. The Authority introduced toll free numbers as well as dedicated Customer Service Office to provide customers with the necessary assistance they might need. The Authority’s website was revamped to comply with technological changes and help provide a better user experience. Social media engagements were done as part of customer engagement, media relations, and community relations.

Going Forward

The Authority will continue to drive public awareness of the regulator and its operation in both urban and rural areas as this will help promote public confidence and build trust and transparency in the medicines regulatory affairs in the fulfilment of the Authority’s mandate in line with the National Development Strategy 1 (NDS1).

▶ Legal and Corporate Affairs

Introduction

The Legal Unit provides strategic legal counsel, ensures regulatory compliance, manages risks, and protects the interests of the Authority to enable success and minimize legal exposure.

Activities

The Legal Unit is involved in the following key activities:

1. Legal risk assessment and management.
2. Reviewing and developing of legislation.
3. Drafting and reviewing of contracts.
4. Rendering legal advice to the Director-General, all Units/Divisions and Committees of the Authority.
5. Interpretation of legislation
6. Coordination of cases for litigation with MCAZ external legal counsel.
7. Monitoring compliance of the Authority to Corporate Governance issues.
8. Providing secretariat services to the Legal and Hearing Committees and the Legal Drafting Sub-Committee.

Capacity Development Issues Undertaken.

In 2023, one Legal Officer attended the Law Society of Zimbabwe Winter School where topics that enhance the effectiveness of the Legal Unit were discussed. These included discussions on the pros and cons of using artificial intelligence (AI) by lawyers and the synergies between lawyers in practice and corporate lawyers.

Key/Notable Achievements

In 2023, the Unit finalized and submitted draft regulations to the Minister of Health and Child Care. The following regulations were submitted for approval:

- i. Medicines and Allied Substances Control (Personal Protective Equipment) Regulations,
- ii. Medicines and Allied Substances Control (Hand Sanitiser) Regulations,
- iii. Medicines and Allied Substances Control (Active Pharmaceutical Ingredients) Regulations, and
- iv. Medicines and Allied Substances Control (Medicated Feed) Regulations.

The Ministry of Health and Child Care also approved the concept note, that was submitted by the Unit on the proposed amendments to the Medicines and Allied Substances Control Act (Chapter 15:03) and granted authority for the MCAZ to consult stakeholders on the proposed amendments.

Seven (7) hearings were conducted in 2023 and the Legal Unit continued to provide secretariat services and guidance to the Hearing Committee as it carried out its mandate of hearing matters involving contraventions of the law.

Lessons Learnt And Challenges

The Authority needs enabling legislation to fulfil its mandate. However, the Authority has not been able to effectively fulfil its mandate due to the delays in the approval of its legislation. There is need for continuous engagement and involvement of the Ministry of Health and Child Care to expedite the approval of the pending legislation.

The Unit noted that the Corporate Governance Unit was ready to assist and provide guidance to the Authority on any corporate governance issues.

Plans For the Future.

The Unit intends to create a rapport between the Authority and the new administration at the Ministry of Health and Child Care to facilitate approval of legislation.

On the corporate governance front, the Unit will continue conducting self-assessments of the Authority's compliance to the corporate governance framework. This will assist in improving the Authority's compliance. The Unit will also continue requesting for assistance from the Corporate Governance Unit if need be.

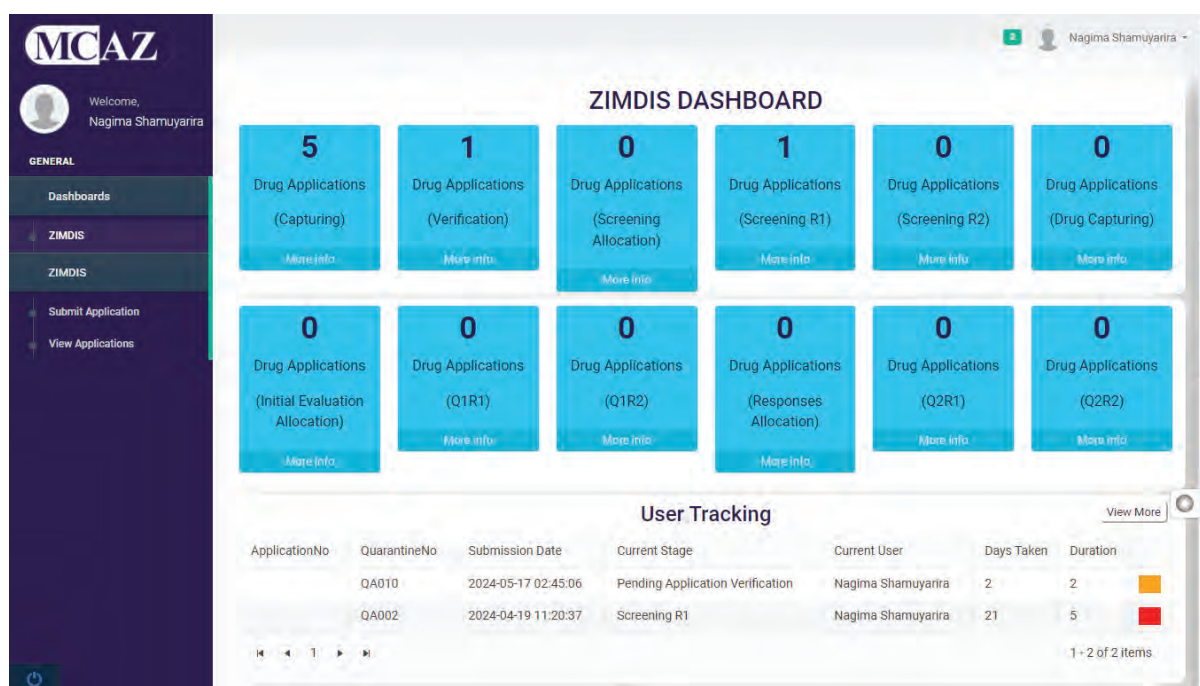


Information and Communication Technology

The ICT Unit drives the Authority’s automation of key business processes. This is achieved through providing a combination of in-house software development solutions and international collaboration solutions. The unit is driving the strategic goal to fully automate by 2026.

Key/Notable Achievements

The Authority developed a new Zimbabwe Drug Information System (ZIMDIS). The system was developed internally with the MCAZ developers. The system is used for Drug registrations and the evaluation process.



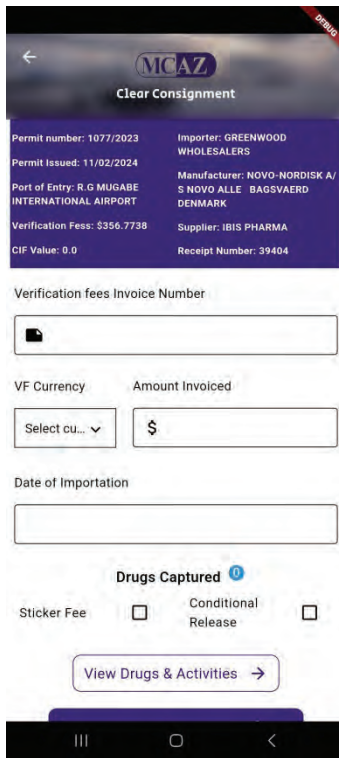
Screenshot of the system used to track Drug Applications

The Unit has also managed to implement Microsoft Azure for the key systems which have lots of benefits such as:

1. Cloud-based access to the platform.
2. Increased system availability through distributed access,
3. Cost-effective use of the platform,

This saw the systems migrated to this platform for easier access and systems maintenance.

The Unit developed the mobile consignment clearance for Imports and Exports of Medicines bringing convenience and ease of clearing drugs



The screenshot shows the 'Clear Consignment' screen in the MCAZ mobile application. It displays the following information:

- Permit number: 1077/2023
- Importer: GREENWOOD WHOLESALERS
- Permit Issued: 11/02/2024
- Manufacturer: NOVO-NORDISK A/S NOVO ALLE BAGSVAERD DENMARK
- Port of Entry: R.G MUGABE INTERNATIONAL AIRPORT
- Supplier: IBIS PHARMA
- Verification Fees: \$356.7738
- CIF Value: 0.0
- Receipt Number: 39404

Below the information, there are input fields for 'Verification fees Invoice Number', 'VF Currency' (with a dropdown menu), and 'Amount Invoiced' (with a '\$' symbol). There is also a 'Date of Importation' field. A 'Drugs Captured' section shows 'Sticker Fee' and 'Conditional Release' with checkboxes. A 'View Drugs & Activities' button is at the bottom.



The Unit closed most of the efficiency gaps of the following systems.

- i. Import and Export of registered medicines.
- ii. Import and Export of Narcotics
- iii. Import and Export of unregistered Medicines (Section 75 Authorisation)
- iv. Renewal of Persons and Premises Licenses.

The Unit was able to upgrade some of its IT Infrastructure such as San-Storage which uses faster SSD for processing.

Lessons Learnt

ICT Staff need to use modern and robust technologies in their daily operations especially the development team to align with the Authority strategies with the ultimate goal of implementing efficient systems. Also, ICT infrastructure such as internet and hardware (laptops) needs to be adequate to be able to provide online support services and support business applications.

Plans For the Future

- i. To implement IRMIS as a key enabler for streamlining authority business processes including data integrity, tracking of activities, and aligning this to the GBT Maturity Level 3 requirements.
- ii. To implement an online portal for processing applications for the issuing of new premises and persons.
- iii. To implement a payment portal and CRM to allow users to make payments for their applications online.
- iv. To implement an online portal for both Local inspections and GMP Inspections.
- v. Full automation of retention fees processing system.
- vi. To implement a mobile application for Drug lookup.

A person wearing a blue shirt is shown from the chest down, sitting at a wooden desk. They are holding a black calculator in their right hand and a black pen in their left hand. The pen is held over an open notebook with lined pages. The calculator is also on the desk, and the person's left hand is positioned as if they are about to use it. The background is slightly blurred, showing more of the desk and the person's shirt. A dark blue banner with rounded corners is overlaid on the top left of the image, containing the text 'Audited Financial Statements' in white, preceded by a green triangle icon.

▶ Audited Financial Statements

All communication should be addressed to:
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OFFICE OF THE AUDITOR-GENERAL
5th Floor, Burroughs House,
48 George Silundika Avenue,
Harare

Ref: **I/69/534**



REPORT OF THE AUDITOR-GENERAL
TO
THE MINISTER OF HEALTH AND CHILD CARE
AND
THE BOARD OF DIRECTORS
IN RESPECT OF THE CONSOLIDATED FINANCIAL STATEMENTS OF
MEDICINES CONTROL AUTHORITY OF ZIMBABWE
FOR THE YEAR ENDED DECEMBER 31, 2023

Report on the Audit of the Consolidated Financial Statements

I have audited the consolidated financial statements of the Medicines Control Authority of Zimbabwe and its subsidiary ("the Group") as set out on pages 7 to 31, which comprise the consolidated statement of financial position as at December 31, 2023, and the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in reserves and consolidated statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

Opinion on the Consolidated Financial Statements

In my opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of Medicines Control Authority of Zimbabwe as at December 31, 2023, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRSs).

Opinion on the Authority's Financial Statements

In my opinion, the financial statements present fairly, in all material respects, the financial position of Medicines Control Authority of Zimbabwe as at December 31, 2023, and its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRSs).

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS
for the year ended December 31, 2023

Basis for Opinion

I conducted my audit in accordance with International Standards on Auditing (ISAs) and International Standards of Supreme Audit Institutions (ISSAIs). My responsibilities under those standards are further described in the Auditor’s Responsibilities for the Audit of the Financial Statements section of my report. I am independent of the Group in accordance with the ethical requirements that are relevant to my audit of the financial statements, and I have fulfilled my other ethical responsibilities in accordance with these requirements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Key Audit Matters

Key Audit Matters are those matters that, in my professional judgment, were of most significance in my audit of the consolidated financial statements of the Medicines Control Authority of Zimbabwe for the year ended December 31, 2023. These matters were addressed in the context of my audit of the consolidated financial statements as a whole, and in forming my opinion thereon, and I do not provide a separate opinion on these matters. I have determined the matters described below to be the key audit matters to be communicated in my report.

Key Audit Matter	How my audit addressed the Key Audit Matter
<p>Valuation of trade receivables. Refer to notes 3.4.1.2 and 9 of the financial statements</p> <p>Management has estimated the recoverable amount of trade receivables for the Group to be ZWL\$ 2.2 billion as at December 31, 2023 after adjusting allowance for credit losses of ZWL\$129.2 million.</p> <p>The determination of recoverability of the receivables and the allowance for credit losses requires significant judgement from management. The level of judgement required in calculating the probability of default increases the risk that allowances may not be appropriately determined. As a result, the valuation of receivables was significant to my audit and therefore considered a key audit matter.</p>	<p>The audit procedures that I performed to address the risk of material misstatement relating to valuation of trade receivables included:</p> <ul style="list-style-type: none"> • Assessed the recoverability of material long outstanding receivables by making comparison of the rate of collection in the current year and prior year. • Analysed the debtors’ age analysis for the long outstanding amounts and reasonability of provision for irrecoverable amounts. • Tested the accuracy and completeness of receivables age analysis through debtors’ confirmations. • Tested on the reasonableness of management assumptions and judgement used in establishing loss default considering the nature and suitability of any historic data used to support these assumptions. • Evaluated the reasonability of management judgements and recalculating the allowance for credit losses assumptions made in estimating the allowance for credit losses.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS
for the year ended December 31, 2023

Key Audit Matter	How my audit addressed the Key Audit Matter
	Based on the evidence gathered, I found the valuation of the Group trade receivables to be reasonable.
<p>Valuation of property, plant and equipment, refer to notes 3.1 and 4 to the financial statements.</p> <p>The Group held property, plant and equipment with a revalued carrying amount of ZWL\$ 37.9 billion as at December 31, 2023 after adjusting for revaluation surplus of ZWL\$ 14.7 billion.</p> <p>A property valuation expert was engaged to conduct revaluation of the Authority's land and buildings. Valuation techniques takes into account valuer's assumptions, unobservable inputs and therefore requires significant judgement in determining the fair value of the assets.</p> <p>As a result, valuation of property, plant and equipment was considered to be a key audit matter.</p>	<p>The audit procedures that I performed to address the risk of material misstatement relating to valuation of investment property included:</p> <ul style="list-style-type: none"> • Reviewed whether there is adequate documentation /policy to support the assumptions that property, plant and equipment reflect the existing economic conditions and existing business circumstances. • Reviewed whether the revaluation was in compliance with International Accounting Standard 16- "Property, plant and equipment". • Evaluate management's estimates regarding determination of useful lives and residual values of assets in relation to the Authority's historical experience, industry practice and future operating plans. • Critically evaluate the methodology and assumptions used by property valuer when performing the valuation. <p>Based on the evidence gathered, I found that the Group's property, plant and equipment was appropriately valued and adequate disclosures related to property, plant and equipment in the financial statements were appropriate.</p>
<p>Valuation of investment property, refer to notes 3.1.6 and 5 to the financial statements.</p> <p>The Group's investment property fair value increased from ZWL\$ 1.06 billion to ZWL\$11.4 billion. Valuation of the investment property is highly subjective due to the use of judgments and estimates.</p> <p>The fair value determination of investment property was dependent on the valuation methodology adopted and the inputs into the valuation model. This method also took into</p>	<p>The audit procedures that I performed to address the risk of material misstatement relating to valuation of investment property included:</p> <ul style="list-style-type: none"> • Reviewed whether there was adequate documentation/policy to support the assumptions that investment properties reflect the existing economic conditions and existing business circumstances. • Reviewed the assumptions used for valuation of investment property carried at fair value. • Reviewed whether the basis of assumptions used comply with International Financial

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS
for the year ended December 31, 2023

Key Audit Matter	How my audit addressed the Key Audit Matter
<p>account use of unobservable inputs and therefore required significant judgement in determining the fair value of the assets.</p> <p>As a result of the significance of the investment property balance and the judgements applied by management in determining the fair values, the valuation of investment property was considered a key audit matter.</p>	<p>Reporting Standard 13- "Fair value measurement".</p> <p>Based on the evidence gathered ,I found that the Group's investment property was fairly valued and disclosures related to investment property were appropriate.</p>

Other Information

The Management is responsible for the other information. The other information comprises all the information in the Medicines Control Authority of Zimbabwe's 2023 annual report as required by the Public Finance Management Act [Chapter 22:19] and the Medicines and Allied Substances Control Act [Chapter 15:03] other than the financial statements and my auditor's report thereon.

My opinion on the Group's financial statements does not cover the other information and I do not express any form of assurance conclusion thereon.

In connection with my audit of the Group's financial statements, my responsibility is to read the other information and in doing so, consider whether the other information is materially inconsistent with the Group's financial statements or my knowledge obtained in the audit or otherwise appears to be materially misstated. If, based on the work I have performed, I conclude that there is a material misstatement of the other information, I am required to report that fact. I have nothing to report in this regard.

Responsibilities of Management and Those Charged with Governance for the consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with International Financial Reporting Standards (IFRSs) and in the manner required by the Medicines and Allied Substances Control Act [Chapter 15:03] and for such internal controls as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Group or cease operations or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the Group's financial reporting process.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS
for the year ended December 31, 2023

Auditor's Responsibilities for the Audit of the consolidated Financial Statements

The objectives of my audit are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatements, whether due to fraud or error, and to issue an auditor's report that includes my opinion. Reasonable assurance is a high level of assurance, but it is not a guarantee that an audit conducted in accordance with ISAs and ISSAIs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with ISAs and ISSAIs, I exercise professional judgment and maintain professional skepticism throughout the planning and performance of the audit. I also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosure, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities which the Group to express an opinion on the consolidated financial statements. I am responsible for the direction, supervision and performance of the Group audit. I remain solely responsible for my audit opinion.

I communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that I identify during my audit.

I also provide those charged with governance a statement that I have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS
for the year ended December 31, 2023

and other matters that may reasonably be thought to bear on my independence, and where applicable, related safeguards.

From the matters communicated with those charged with governance, I determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. I describe these matters in my auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, I determine that a matter should not be communicated in my report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on Other Legal and Regulatory Requirements

In my opinion, the consolidated financial statements of Medicines Control Authority of Zimbabwe have, in all material respects, been properly prepared in compliance with the disclosure requirements of the Medicines and Allied Substances Control Act [*Chapter 15:03*], Public Finance Management Act [*Chapter 22:19*] and other relevant Statutory Instruments.

30 July, 2024.



R. KUJINGA,
ACTING AUDITOR-GENERAL.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
CONSOLIDATED STATEMENT OF FINANCIAL POSITION

as at December 31, 2023

MCAZ GROUP

AUTHORITY

ASSETS	Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	2023 ZWL\$	2022 ZWL\$	2023 ZWL\$	2022 ZWL\$	2023 ZWL\$	2022 ZWL\$	2023 ZWL\$	2022 ZWL\$
Non-current assets	49 439 991 057	22 146 074 583	45 430 316 547	4 608 340 790	46 496 119 822	20 364 989 768	41 605 532 865	4 054 595 711
Property, plant and equipment	37 943 073 764	17 052 378 625	33 933 399 254	3 548 340 790	34 117 009 291	14 389 100 572	30 108 396 977	2 994 377 116
Investment property	11 475 000 000	5 093 695 958	11 475 000 000	1 060 000 000	11 475 000 000	5 093 695 958	11 475 000 000	1 060 000 000
Investment in subsidiary	-	-	-	-	882 193 238	882 193 238	218 595	-
Other long term financial assets	21 917 293	-	21 917 293	-	21 917 293	-	21 917 293	-
Current assets	25 031 657 681	15 744 361 711	24 129 656 030	3 169 960 820	24 720 358 010	15 548 409 722	23 818 356 359	3 129 183 139
Inventory	869 758 578	584 720 529	326 012 138	15 233 921	869 758 578	584 720 529	326 012 138	15 233 921
Trade and other receivables	2 243 687 183	1 330 283 759	2 243 687 183	276 832 539	2 229 489 444	1 338 754 480	2 229 489 444	278 595 299
Prepayments	1 021 940 460	334 245 743	663 685 249	69 556 662	1 021 940 460	334 245 743	663 685 249	69 556 662
Cash and cash equivalents	20 889 231 460	13 495 111 680	20 889 231 460	2 808 337 698	20 592 129 528	13 290 688 970	20 592 129 528	2 765 797 257
Non current assets held for sale	7 040 000	-	7 040 000	-	7 040 000	-	7 040 000	-
Total assets	74 471 648 738	37 890 436 294	69 559 972 577	7 778 301 610	71 216 477 832	35 913 399 490	65 423 889 224	7 183 778 850
RESERVES AND LIABILITIES								
Reserves	64 043 764 955	32 864 760 509	61 134 653 246	7 125 601 759	61 714 858 333	31 595 263 159	57 883 022 340	6 683 913 374
Capital reserve	6 275 362 916	6 275 362 916	5 444 017	5 444 017	6 275 362 916	6 275 362 916	5 444 017	5 444 017
Accumulated fund	28 739 274 990	12 031 979 598	33 117 412 802	3 698 709 899	29 765 579 736	13 105 617 907	33 033 764 091	3 784 780 847
Revaluation reserve	26 272 780 817	11 916 114 594	26 570 631 049	3 138 198 665	25 673 915 681	12 214 282 336	24 843 814 232	2 893 688 510
Non-controlling interest	2 756 346 232	2 641 303 401	1 441 165 378	283 249 178	-	-	-	-
Non-current liabilities	2 985 435 898	2 656 784 215	982 871 446	159 732 645	1 659 345 078	1 972 487 761	9 872 132	11 735 147
Deferred income	1 970 624 745	1 972 487 763	9 872 131	11 735 147	1 659 345 078	1 972 487 761	9 872 132	11 735 147
Deferred tax	1 014 811 153	684 296 452	972 998 315	147 997 498	-	-	-	-
Current liabilities	7 442 447 885	2 368 891 570	7 442 447 885	492 967 206	7 842 274 421	2 345 648 570	7 530 994 752	488 130 329
Trade and other payables	7 355 903 116	2 310 937 107	7 355 903 116	480 906 861	7 444 449 983	2 287 694 107	7 444 449 983	476 069 984
Provisions	84 681 753	48 796 132	84 681 753	10 154 493	84 681 753	48 796 132	84 681 753	10 154 493
Deferred income	1 863 016	9 158 331	1 863 016	1 905 852	313 142 685	9 158 331	1 863 016	1 905 852
Total reserves and liabilities	74 471 648 738	37 890 436 294	69 559 972 577	7 778 301 610	71 216 477 832	35 913 399 490	65 423 889 224	7 183 778 850

22/07/2024, 2024.

22/07/2024, 2024.

23/7/2024, 2024.

R. B. Tugwete
R. B. Tugwete, MBA, BSc (Hon) in Applied Accounting, BBA Business
Management, ACCA
(HEAD FINANCE).

R. T. Rukwata
R. T. Rukwata,
(DIRECTOR-GENERAL).

M. M. Chiware
Dr. M. Chiware,
(CHAIRMAN).

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
for the year ended December 31, 2023

Note	MCAZ GROUP						AUTHORITY					
	Inflation adjusted		Historical cost		Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	2023	2022	2023	2022	2023	2022	2023	2022	2023	2022	2023	2022
	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$
INCOME	101 223 786 223	28 084 183 376	55 114 095 945	5 215 090 898	100 881 288 070	27 844 612 712	54 788 768 710	5 171 231 453	36 855 736 524	11 580 525 751	21 184 831 317	1 583 248 756
Medicines control income	36 855 736 524	11 580 525 751	21 184 831 317	1 583 248 756	36 855 736 524	11 580 525 751	21 184 831 317	1 583 248 756	5 993 921 607	2 574 149 824	4 238 486 922	407 295 294
Laboratory services	5 993 921 607	2 574 149 824	4 238 486 922	407 295 294	58 031 629 939	13 689 937 137	29 365 450 471	3 180 687 403	58 031 629 939	13 689 937 137	29 365 450 471	3 180 687 403
Other income	58 374 128 092	13 929 507 801	29 690 777 706	3 224 546 848	(46 907 097 592)	(13 927 902 267)	(25 540 974 743)	(2 017 556 269)	(47 296 630 430)	(14 030 356 818)	(25 556 243 844)	(2 017 556 269)
LESS EXPENDITURE	(47 296 630 430)	(14 030 356 818)	(25 556 243 844)	(2 036 814 435)	(46 907 097 592)	(13 927 902 267)	(25 540 974 743)	(2 017 556 269)	(25 751 423 326)	(5 779 623 478)	(12 528 491 186)	(786 930 204)
Administration expenses	(25 751 423 326)	(5 779 623 478)	(12 528 491 186)	(806 188 370)	(253 618 900 488)	(5 677 188 926)	(12 513 222 085)	(786 930 204)	(21 545 207 104)	(8 250 733 341)	(13 027 752 658)	(1 230 626 065)
Other expenses	(21 545 207 104)	(8 250 733 340)	(13 027 752 658)	(1 230 626 065)	(21 545 207 104)	(8 250 733 341)	(13 027 752 658)	(1 230 626 065)	53 927 155 793	14 053 826 558	29 557 852 101	3 178 276 463
Operating surplus for the year	(37 202 176 086)	(7 011 554 500)	(29 557 852 101)	3 178 276 463	53 974 190 478	13 916 710 445	29 247 793 967	3 153 675 184	(37 202 176 086)	(7 011 554 500)	-	-
Monetary (loss)					(37 315 417 927)	(6 044 283 978)						
Surplus before taxation	16 724 979 707	7 042 272 058	29 557 852 101	3 178 276 463	16 658 772 551	7 872 426 467	29 247 793 967	3 153 675 184	16 724 979 707	7 042 272 058	29 557 852 101	3 178 276 463
Income tax expense	(10 500 893)	(6 047 928)	(10 500 893)	(1 258 576)	-	-	-	-	(10 500 893)	(6 047 928)	(10 500 893)	(1 258 576)
Surplus after taxation	16 714 478 814	7 036 224 130	29 547 351 208	3 177 017 887	16 658 772 551	7 872 426 467	29 247 793 967	3 153 675 184	16 714 478 814	7 036 224 130	29 547 351 208	3 177 017 887
Other comprehensive income												
Revaluation surplus	14 467 341 917	7 390 027 106	24 463 699 172	2 743 924 219	13 460 822 623	5 758 297 327	21 951 315 000	2 373 903 278	14 467 341 917	7 390 027 106	24 463 699 172	2 743 924 219
Total other comprehensive income	14 467 341 917	7 390 027 106	24 463 699 172	2 743 924 219	13 460 822 623	5 758 297 327	21 951 315 000	2 373 903 278	14 467 341 917	7 390 027 106	24 463 699 172	2 743 924 219
Total comprehensive income	31 181 820 731	14 426 251 236	54 011 050 380	5 920 942 106	30 119 595 174	13 630 723 794	51 199 108 967	5 527 578 462	31 181 820 731	14 426 251 236	54 011 050 380	5 920 942 106
Surplus for the year attributable to:												
Equity holders of the parent	16 708 922 399	7 009 523 480	29 419 512 518	3 167 447 380	16 658 772 551	7 872 426 467	29 247 793 967	3 153 675 184	16 708 922 399	7 009 523 480	29 419 512 518	3 167 447 380
Non-controlling interest	5 556 415	26 700 650	127 838 690	9 570 507	-	-	-	-	5 556 415	26 700 650	127 838 690	9 570 507
Surplus for the year	16 714 478 814	7 036 224 130	29 547 351 208	3 177 017 887	16 658 772 551	7 872 426 467	29 247 793 967	3 153 675 184	16 714 478 814	7 036 224 130	29 547 351 208	3 177 017 887
Other comprehensive income attributable to:												
Equity holders of the parent	14 357 855 501	6 863 903 984	23 433 621 662	2 592 215 633	13,460,822,623	5 758 297 327	21 951 315 000	2 373 903 278	14 357 855 501	6 863 903 984	23 433 621 662	2 592 215 633
Non-controlling interest	109 486 416	526 123 122	1 030 077 510	151 708 586	-	-	-	-	109 486 416	526 123 122	1 030 077 510	151 708 586
Surplus for the year	14 467 341 917	7 390 027 106	24 463 699 172	2 743 924 219	13 460 822 623	5 758 297 327	21 951 315 000	2 373 903 278	14 467 341 917	7 390 027 106	24 463 699 172	2 743 924 219

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
STATEMENT OF CHANGES IN RESERVES

for the year ended December 31, 2023

Group Inflation adjusted	Accumulated	Capital	Revaluation	Total	Non-	Total
	fund	reserve	reserve		controlling	reserves
	ZWLS	ZWLS	ZWLS	ZWLS	interest	ZWLS
					ZWLS	
Balance as at January 1, 2022	5 007 537 720	6 275 362 916	5 067 129 008	16 350 029 644	2 088 479 629	18 438 509 273
Surplus for the year	7 009 523 480	-	-	7 009 523 480	26 700 650	7 036 224 130
Gain on revaluation of assets	-	-	6 863 903 984	6 863 903 984	526 123 122	7 390 027 106
Utilization of revaluation reserve on disposed assets	14 918 398	-	(14 918 398)	-	-	-
Balance as at December 31, 2022	12 031 979 598	6 275 362 916	11 916 114 594	30 223 457 108	2 641 303 401	32 864 760 509
Balance as at January 1, 2023	12 031 979 598	6 275 362 916	11 916 114 594	30 223 457 108	2 641 303 401	32 864 760 509
Surplus for the year	16 708 922 399	-	-	16 708 922 399	5 556 415	16 714 478 814
Gain on revaluation of assets	-	-	14 357 855 501	14 357 855 501	109 486 416	14 467 341 917
Dividend paid	(2 816 285)	-	-	(2 816 285)	-	(2 816 285)
Utilization of revaluation reserve on disposed assets	1 189 278	-	(1 189 278)	-	-	-
Balance as at December 31, 2023	28 739 274 990	6 275 362 916	26 272 780 817	61 287 418 723	2 756 346 232	64 043 764 955
Historical cost						
Balance as at January 1, 2022	526 564 516	5 444 017	550 681 035	1 082 689 568	121 970 085	1 204 659 653
Surplus for the year	3 167 447 380	-	-	3 167 447 380	9 570 507	3 177 017 887
Gain on revaluation of assets	-	-	2 592 215 633	2 592 215 633	151 708 586	2 743 924 219
Utilization of revaluation reserve on disposed assets	4 698 003	-	(4 698 003)	-	-	-
Balance as at December 31, 2022	3 698 709 899	5 444 017	3 138 198 665	6 842 352 581	283 249 178	7 125 601 759
Balance as at January 1, 2023	3 698 709 899	5 444 017	3 138 198 665	6 842 352 581	283 249 178	7 125 601 759
Surplus for the year	29 419 512 518	-	-	29 419 512 518	127 838 690	29 547 351 208
Dividend paid	(1 998 892)	-	-	(1 998 892)	-	(1 998 892)
Gain on revaluation of assets	-	-	23 433 621 662	23 433 621 662	1 030 077 510	24 463 699 172
Utilization of revaluation reserve on disposed assets	1 189 278	-	(1 189 278)	-	-	-
Balance as at December 31, 2023	33 117 412 802	5 444 017	26 570 631 049	59 693 487 869	1 441 165 378	61 134 653 247

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
STATEMENT OF CHANGES IN RESERVES

	for the year ended December 31, 2023			
Authority	Accumulated fund ZWL\$	Capital reserve ZWL\$	Revaluation reserve ZWL\$	Total ZWL\$
Inflation adjusted				
Balance as at January 1, 2022	5 218 273 042	6 275 362 916	6 470 903 407	17 964 539 365
Surplus for the year	7 872 426 467	-	-	7 872 426 467
Gain on revaluation of assets	-	-	5 758 297 327	5 758 297 327
Utilization of revaluation reserve on disposed assets	14 918 398	-	(14 918 398)	-
Balance as at December 31, 2022	13 105 617 907	6 275 362 916	12 214 282 336	31 595 263 159
Balance as at January 1, 2023	13 105 617 907	6 275 362 916	12 214 282 336	31 595 263 159
Surplus for the year	16 658 772 551	-	-	16 658 772 551
Gain on revaluation of assets	-	-	13 460 822 623	13 460 822 623
Utilization of revaluation reserve on disposed assets	1 189 278	-	(1 189 278)	-
Balance as at December 31, 2023	29 765 579 736	6 275 362 916	25 673 915 681	61 714 858 333
Authority				
Historical cost				
Balance as at January 1, 2022	626 407 660	5 444 017	524 483 235	1 156 334 912
Surplus for the year	3 153 675 184	-	-	3 153 675 184
Gain on revaluation of assets	-	-	2 373 903 278	2 373 903 278
Utilization of revaluation reserve on disposed assets	4 698 003	-	(4 698 003)	-
Balance as at December 31, 2022	3 784 780 847	5 444 017	2 893 688 510	6 683 913 374
Balance as at January 1, 2023	3 784 780 847	5 444 017	2 893 688 510	6 683 913 374
Surplus for the year	29 247 793 967	-	-	29 247 793 967
Gain on revaluation of assets	-	-	21 951 315 000	21 951 315 000
Utilization of revaluation reserve on disposed assets	1 189 278	-	(1 189 278)	-
Balance as at December 31, 2023	33 033 764 091	5 444 017	24 843 814 232	57 883 022 341

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
CONSOLIDATED STATEMENT OF CASH FLOWS

for the year ended December 31, 2023

	Note	MCAZ GROUP							
		Inflation adjusted		Historical cost		AUTHORITY			
		2023 ZWL\$	2022 ZWL\$	2023 ZWL\$	2022 ZWL\$	2023 ZWL\$	2022 ZWL\$		
Net cash flow from operating activities		2 489 585 401	6 648 158 207	5 592 304 635	1 319 555 783	2 835 671 308	6 436 622 128	5 651 237 172	1 279 684 256
Surplus for the year		16 724 979 707	7 042 272 058	29 557 862 101	3 178 276 463	16 658 772 551	7 872 426 467	29 247 793 967	3 153 675 184
Adjusted for non cash items:		(17 392 199 279)	106 5 646 782	(27 979 604 086)	(1 885 873 612)	(17 116 389 389)	5 6 828 063	(27 709 135 845)	(1 894 474 119)
Depreciation charge for the year		1 291 651 292	991 486 962	403 283 328	36 817 109	1 117 403 716	949 938 765	336 935 943	28 216 602
Increase in provision for leave pay		328 688 877	30 276 222	74 527 260	6 300 492	328 688 877	30 276 222	74 527 260	6 300 492
Fair value adjustment on investment property		(6 381 304 042)	(1 748 591 575)	(10 415 000 000)	(857 498 900)	(6 381 304 042)	(1 748 591 575)	(10 415 000 000)	(857 498 900)
Fair value adjustment on equity shares		(3 960 918)	(3 960 918)	(3 960 918)	(3 960 918)	(3 960 918)	(3 960 918)	(3 960 918)	(3 960 918)
Deferred income amortisation		(9 158 331)	(17 867 412)	(1 905 852)	(2 047 368)	(9 158 331)	(17 867 412)	(1 905 852)	(2 047 368)
Loss on disposal of property, plant and equipment		1 167 626	49 168 678	1 027 292	3 564 649	1 167 626	49 168 678	1 027 292	3 564 649
Interest earned		(631 331 642)	(25 582 925)	(580 203 272)	(4 534 870)	(631 331 642)	(25 582 925)	(580 203 272)	(4 534 870)
Exchange gains-unrealised		(49 190 128 227)	(5 224 797 668)	(17 457 371 924)	(1 068 474 724)	(48 853 312 602)	(5 224 797 668)	(17 120 556 298)	(1 068 474 724)
Net Monetary loss		37 202 176 086	701 1 554 500	-	-	37 315 417 927	604 4 283 978	-	-
Working capital changes:		3 156 804 973	(1459 760 633)	4 014 056 620	27 159 932	3 293 288 146	(1492 632 402)	4 112 579 050	20 483 191
Increase in inventory		(285 038 049)	(550 499 240)	(310 778 217)	(13 189 884)	(285 038 049)	(550 499 240)	(310 778 217)	(13 189 884)
Increase in trade and other receivables		(915 428 270)	(1 314 374 734)	(1 956 032 831)	(325 192 037)	(890 734 964)	(1 324 093 247)	(1 950 894 145)	(327 030 334)
Increase in prepayments		(687 694 717)	-	(594 128 587)	-	(687 694 717)	-	(594 128 587)	-
Increase in trade and other payables		5 044 966 009	405 113 341	6 874 996 255	365 534 853	5 156 755 876	381 960 085	6 968 379 999	360 703 409
Income tax paid		(32 801 485)	(6 047 928)	(21 322 706)	(1 258 576)	-	-	-	-
Net cash flow from investing activities:		(6 808 787 953)	(338 170 402)	(4 947 460 091)	(103 562 827)	(6 805 971 666)	(338 170 402)	(4 945 461 199)	(103 562 827)
Purchase of property, plant and equipment		(7 419 346 935)	(375 077 478)	(5 507 708 096)	(108 274 213)	(7 419 346 935)	(375 077 478)	(5507 708 096)	(108 274 213)
Proceeds from disposal of property, plant and equipment		-	11 324 151	-	176 516	631 331 642	11 324 151	580 203 272	176 516
Interest received		631 331 642	25 582 925	(17 956 375)	4 534 870	(17 956 375)	25 582 925	(17 956 375)	4 534 870
Purchase of equity investment		(17 956 375)	-	(1 998 892)	-	-	-	-	-
Dividend paid		(2 816 285)	-	(1 998 892)	-	-	-	-	-
Net (decrease)/increase in cash and cash equivalents		(435 200 4037)	6 303 939 877	623 521 838	1 214 734 380	(3970 300 360)	6 098 451 726	705 775 973	1 176 121 429
Effects of inflation on cash and cash equivalents		(37 444 004 410)	(6 708 195 867)	-	-	(37 581 571 684)	(6 642 252 400)	-	-
Unrealised exchange gain on cash and cash equivalents		49 190 128 227	5 224 797 668	17 457 371 924	1 068 474 722	48 853 312 602	5 224 797 668	17 120 556 298	1 068 474 724
Cash and cash equivalents at beginning of the year		13 495 111 680	8 674 570 002	2 808 337 698	525 128 596	13 290 688 970	8 609 691 976	2 765 797 257	521 201 104
Cash and cash equivalents at year end		20 889 231 460	13 495 111 680	20 889 231 460	2 808 337 698	20 592 129 528	13 290 688 970	20 592 129 528	2 765 797 257

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
for the year ended December 31, 2023

1. NATURE OF BUSINESS

The Medicines Control Authority of Zimbabwe was established by the Medicines and Allied Substances Control Act [*Chapter 15:03*] and became operational from August 1, 1997. The main purpose of the Authority is to ensure the availability of safe and effective medicines on the market for human and animal consumption. The purpose of the Act was to create an autonomous institution able to operate as a business entity.

2. BASIS OF PREPARATION

2.1 Statement of compliance

The Group's financial statements have been prepared in accordance with International Financial Reporting Standards (IFRSs) as issued by the International Accounting Standards Board (IASB) and interpretations issued by the IFRS Interpretations Committee ("IFRS IC") as issued by the International Accounting Standards Board ("IASB"). The Group has prepared the financial statements on the basis that it will continue to operate as a going concern. Management considered that there are no material uncertainties that may cast significant doubt over this assumption. In so doing, Management formed a judgement that there is a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future, and not less than 12 months from the end of the reporting period.

2.2 Basis of measurement

The Group's financial statements are based on the statutory records that are maintained under the historical cost basis, except for property, plant and equipment shown at revalued amounts and Investment property which is measured at fair value.

2.2.1 Inflation Accounting

The financial statements have been prepared under the current costs basis in line with the provisions of International Accounting Standards (IAS) 29 – "Financial Reporting in Hyperinflationary economies". In 2019, the Public Accountants and Auditors board (PAAB) pronounced that the economy is trading under conditions of hyperinflation, hence entities operating in Zimbabwe with financial periods ending on or after July 1, 2019 are required to prepare and present financial statements in line with the requirements of IAS 29 – "Financial Reporting in Hyperinflationary economies". Management have applied the guidelines provided by PAAB. Management made various assumptions to produce the inflation adjusted financial information, with the significant assumption being use of consumer price indices (CPIs) for the various years. The conversion factors have been computed from the consumer price index (CPI) data as provided by Zimbabwe National Statistics Agency on their website. Below are the indices and adjustment factors used.

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Month	Indices	Conversion Factor
January 2023	13,819.67	4.75
February 2023	13,849.20	4.74
March 2023	13,949.99	4.71
April 2023	15,480.17	4.24
May 2023	18,704.62	3.51
June 2023	42,710.72	1.54
July 2023	46,633.80	1.41
August 2023	42,659.97	1.54
September 2023	44,720.86	1.47
October 2023	49,222.55	1.33
November 2023	53,915.71	1.22
December 2023	65,703.44	1.00
December 2022	13,672.91	4.81
December 2021	3,977.50	16.52
December 2020	2,474.51	26.55

The indices and adjusting factors have been applied to the historical cost of transactions and balances as follows: All items in income statements are restated by applying relevant monthly adjusting factors; The net effect of the inflation adjustments on the net monetary position is included in the income statement as a monetary loss or gain; Comparative information is restated using the inflation indices in terms of the measuring unit current at the reporting date. The application of the IAS 29- "Financial Reporting in Hyperinflationary Economies" restatement procedures has the effect of amending certain accounting policies which are used in the preparation of the financial statements under historical cost convention. The policies affected are monetary assets and liabilities are not restated as they are already stated in terms of the measuring unit current at the reporting date.

2.3 Functional and presentation currency

The financial statements are presented in Zimbabwe Dollars (ZWL\$) which is the Authority's presentation currency. The Authority adopted the United States Dollar (US\$) as the functional currency and all the foreign currency transactions were translated to ZWL\$ using the official rate at the date of the transaction. All the financial information presented has been rounded off to the nearest dollar.

2.4 Critical accounting judgements, assumptions and estimates

In preparing the financial statements, management is required to make estimates and assumptions that affect the amounts presented in the financial statements and related disclosures. Use of available information and the application of judgment is inherent in the formation of estimates. Actual results in the future could differ from these estimates which may be material to the financial statements. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. Significant judgments include the following:

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
for the year ended December 31, 2023

2.4.1 Useful lives and residual values of property, plant and equipment

The Group assesses useful lives and residual values of property, plant and equipment each year taking into account past experience and technology changes. The depreciation rates are set out in note 3.1.2 and no changes to these useful lives have been considered necessary during the year. Management has set residual values for all classes of property, plant and equipment at nil.

2.4.2 Impairment and provisioning policies

At each statement of financial position date, the Authority reviews the carrying amount of its assets to determine whether there is an indication that those assets suffered any impairment. If any such indication exists, the recoverable amount of the assets is estimated to determine the extent of the impairment (if any). If the recoverable amount of an asset is estimated to be less than its carrying amount, the carrying amount of the asset is reduced to its recoverable amount. Impairment is recognised as an expense immediately, unless the relevant asset is carried at a revalued amount, in which case the impairment is treated as a revaluation decrease.

In the event that, in the subsequent period, an asset that has been subject to an impairment loss is no longer considered to be impaired, the value is restored and the gain is recognised in the statement of comprehensive income. The restoration is limited to the value which would have been recorded had the impairment adjustment not taken place.

2.4.3 Fair value measurement

The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either;

- In the principal market for the asset;
- Or
- In the absence of the principal market, in the most advantageous market for the asset.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset, assuming that market participants act in their economic best interest.

External valuers are involved for valuation of land and buildings. Selection criteria for external valuers include market knowledge, reputation, independence and whether professional standards are maintained.

2.4.4 Allowance for credit losses

The Authority uses the general approach model to determine the loss allowance for expected credit losses on debt instruments recorded at amortised cost or at fair value through other comprehensive income. Allowance for credit losses is the estimated amount of loss that will arise from accounts receivables that have been issued but not yet collected. It is computed based on the uncertainty of whether the customer will pay or default. Probability is allocated basing on the trend or payment history of the customer. Provision for credit losses is provided

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
for the year ended December 31, 2023

on receivables that are more than 3 months. We used 100% probability of default for receivables that were more than three (3) months, basing on the trend or payment history of the customer.

2.4.5 Going concern

The Group has prepared the financial statements on the basis that it will continue to operate as a going concern. Management considered that there are no material uncertainties that may cast significant doubt over this assumption. In so doing, Management formed a judgement that there is a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future, and not less than 12 months from the end of the reporting period.

2.4.6 New and amended Standards

2.4.6.1 New standards and amendments effective January 1, 2023

i. Definition of Accounting Estimates - Amendments to International Accounting Standard (IAS) 8- “Accounting Policies, Changes in Accounting Estimates and Errors”

The amendments to IAS 8- “Accounting Policies, Changes in Accounting Estimates and Errors” clarify the distinction between changes in accounting estimates, changes in accounting policies and the correction of errors. They also clarify how entities use measurement techniques and inputs to develop accounting estimates. The amendment had no impact on the Group’s consolidated financial statements.

ii. Disclosure of Accounting Policies - Amendments to International Accounting Standard (IAS) 1- “Presentation of financial statements” and International Financial Reporting Standard Practice Statement 2

The amendments to International Accounting Standard (IAS) 1- “Presentation of financial statements” and IFRS Practice Statement 2 Making Materiality Judgements provide guidance and examples to help entities apply materiality judgements to accounting policy disclosures. The amendments aim to help entities provide accounting policy disclosures that are more useful by replacing the requirement for entities to disclose their ‘significant’ accounting policies with a requirement to disclose their ‘material’ accounting policies and adding guidance on how entities apply the concept of materiality in making decisions about accounting policy disclosures. The amendments have had an impact on the Group’s disclosures of accounting policies, but not on the measurement, recognition or presentation of any items in the Group’s financial statements.

iii. Deferred Tax related to Assets and Liabilities arising from a Single Transaction – Amendments to International Accounting Standard 12- “Income Tax”

The amendments to International Accounting Standard 12- “Income Tax” narrow the scope of the initial recognition exception, so that it no longer applies to transactions that give rise to

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
for the year ended December 31, 2023

equal taxable and deductible temporary differences such as leases and decommissioning liabilities. The amendments had no impact on the Group's consolidated financial statements.

2.4.6.2 Standard and amendments issued in 2023 but effective in future periods

The new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group's financial statements are disclosed below. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

i. Amendments to International Accounting Standard (IAS) 1- "Presentation of financial statements": Classification of Liabilities as Current or Non-current

In January 2020 and October 2022, the IASB issued amendments to paragraphs 69 to 76 of IAS 1- "Presentation of financial statements" to specify the requirements for classifying liabilities as current or non-current. The amendments clarify:

- What is meant by a right to defer settlement
- That a right to defer must exist at the end of the reporting period
- That classification is unaffected by the likelihood that an entity will exercise its deferral right
- That only if an embedded derivative in a convertible liability is itself an equity instrument would the terms of a liability not impact its classification.

In addition, a requirement has been introduced to require disclosure when a liability arising from a loan agreement is classified as non-current and the entity's right to defer settlement is contingent on compliance with future covenants within twelve months. The amendments are effective for annual reporting periods beginning on or after January 1, 2024 and must be applied retrospectively. The amendments are not expected to have a material impact on the Group's financial statements.

ii. Supplier Finance Arrangements - Amendments to International Accounting Standard 7- "Statement of Cash flows" and International Financial Reporting Standard 7- "Financial instruments: Disclosures"

In May 2023, the IASB issued amendments to IAS 7- "Statement of Cash Flows" and IFRS 7- "Financial Instruments: Disclosures" to clarify the characteristics of supplier finance arrangements and require additional disclosure of such arrangements. The disclosure requirements in the amendments are intended to assist users of financial statements in understanding the effects of supplier finance arrangements on an entity's liabilities, cash flows and exposure to liquidity risk. The amendments will be effective for annual reporting periods beginning on or after January 1, 2024. Early adoption is permitted, but will need to be disclosed. The amendments are not expected to have a material impact on the Group's financial statement.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
for the year ended December 31, 2023

iii. International Financial Reporting Standard (IFRS) S1-General Requirements for Disclosure of Sustainability -related Financial Information

IFRS-S1- “General Requirements for Disclosure of Sustainability -related Financial Information” requires an entity to disclose information about all sustainability-related risks and opportunities that could reasonably be expected to affect the entity’s cash flows, its access to finance or cost of capital over the short, medium or long term (collectively referred to as sustainability-related risks and opportunities that could reasonably be expected to affect the entity’s prospects). It prescribes how an entity prepares and reports its sustainability related financial disclosures and sets out general requirements for the content and presentation of those disclosures, so that the information disclosed is useful to users in making decisions relating to providing resources to the entity. The amendments are effective for annual reporting periods on or after January 1, 2024 and will be adopted in that reporting period.

2.5 Basis of Consolidation

The consolidated financial statements comprise the financial statements of the Group and its 59% stake in the subsidiary – Percentage Discount (Private) Limited, as at December 31, 2023.

2.5.1 Subsidiary

Subsidiary is an entity over which MCAZ exercises effective control. Control is achieved when the Authority is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee.

A Subsidiary is fully consolidated from the acquisition date, being the date on which control is transferred to MCAZ and continue to be consolidated until the date that control ceases. On acquisition of subsidiary, the cost of an acquisition is measured as the aggregate of the consideration transferred, measured at acquisition date fair value and the amount of any non-controlling interest in the acquiree. The excess of the cost of acquisition over the fair value of the net assets of the subsidiary acquired is recorded as goodwill.

All intra group balances, income, expenses, unrealized gains, and losses resulting from intra-group transactions are eliminated in full on consolidation. In all material respects, the accounting policies of the subsidiary is consistent with those adopted by the Group.

Non-controlling interests represent the portion of the profit or loss and net assets not held by the Group, and are presently disclosed in profit or loss and within equity in the Group statement of financial position, separate from parent shareholders’ equity. Non-controlling interests are measured at its proportionate share of the net assets acquired.

2.5.2 Change in degree of control

A change in the ownership interest of a subsidiary, without loss of control, is accounted for as an equity transaction.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
for the year ended December 31, 2023

2.5.3 Loss of control

If the Group loses control over a subsidiary, it;

- Derecognises the assets (including goodwill) and liabilities of the subsidiary;
- Derecognises the carrying amount of any non-controlling interest;
- Derecognises the cumulative transaction differences recorded in equity;
- Recognises the fair value of any investment retained;
- Recognises any surplus or deficit in profit or loss;
- Recognises the fair value of the consideration received;
- Reclassifies the parent's share of components previously recognised in other comprehensive income to profit or loss or retained earnings, as appropriate.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
for the year ended December 31, 2023

3 ACCOUNTING POLICIES

The accounting policies applied in the preparation of these financial statements are consistent with those applied in the financial statements for the year ended December 31, 2022.

3.1 Property, plant and equipment

3.1.1 Recognition and measurement

Property, plant and equipment held for use in the supply of services or for administrative purposes, are initially stated at cost. The Authority uses the revaluation model for subsequent measurement of an item of property, plant and equipment where the asset is carried at revalued amount less subsequent depreciation and impairment losses.

3.1.2 Depreciation

Depreciation, which is calculated on the straight line basis, is provided to write off the cost less the estimated residual value of fixed assets over their estimated useful lives. The Group assesses useful life and residual values of property, plant and equipment each year taking into account past experiences and technological changes. No changes to these useful lives have been considered necessary for all other items of property, plant and equipment. Management has set residual values for all classes of property, plant and equipment as zero. Land is not depreciated.

The rates that were applied per annum are as follows:

Furniture, fixtures and fittings	10%
Office equipment	25%
Computer equipment	25%
Motor vehicles-new	20%
Motor vehicles – pre owned	33.3%
Buildings	2.5%
Plant and machinery	10%

3.1.3 Revaluation of property, plant and equipment

Revaluations are performed with sufficient regularity such that the carrying amounts do not differ materially from those that would be determined using fair values at the end of the reporting period. The Authority uses proportionate restatement method when revaluing its assets.

Any revaluation increase arising on the revaluation of property, plant and equipment is recognized in other comprehensive income, except to the extent that it reverses a revaluation decrease for the same asset previously recognized in profit or loss, in which case the increase is credited to profit or loss to the extent of the decrease previously expensed.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
for the year ended December 31, 2023

When an item of property, plant and equipment is revalued, any accumulated depreciation at the date of the revaluation is restated proportionately with the change in the gross carrying amount of the asset so that the carrying amount of the asset after revaluation equals its revalued amount. Upon disposal, any revaluation surplus relating to the particular asset being sold is transferred to retained earnings.

3.1.4 Derecognition of property, plant and equipment

An item of property, plant and equipment and any significant part initially recognized is derecognized upon disposal (i.e. at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of profit or loss when the asset is derecognized.

3.1.5 Leases

The Authority accounts for its leased properties in line with the requirements of International Financial Reporting Standard (IFRS) 16- "Leases". Due to the nature of the agreement with the lessor, the Authority applies the short-term lease recognition exemption to its short-term lease of a building that is used as offices by its staff. Lease payments on short-term leases of 12 months or less are recognized as an expense on a straight-line basis over the lease term.

At Group level, the leased property is accounted for as property, plant and equipment since it is owner occupied by MCAZ (entity within the group). This is in line with IFRS 16- "Leases".

3.1.6 Investment property

Investment property is property held either to earn rental income or for capital appreciation or for both, but not for sale in the ordinary course of business, use in the production or supply of goods or services or for administrative purposes.

Investment property is initially measured at cost. Cost includes expenditure that is directly attributable to the acquisition of the investment property. The cost of self-constructed investment property includes the cost of materials and direct labour, any other costs directly attributable to bringing the investment property to a working condition for their intended use and capitalized borrowing costs.

Subsequently the investment property is measured at fair value at the date of the revaluation less any subsequent accumulated depreciation and subsequent accumulated impairment losses. The revaluation model reflects market conditions at the reporting date. Gains or losses arising from changes in the fair value of the investment property are included in profit or loss in the period in which they arise. Fair values are determined based on an annual valuation performed by an accredited external independent valuer.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
for the year ended December 31, 2023

3.1.7 Intangible Assets

Intangible assets acquired separately are measured on initial recognition at cost. Following initial recognition, intangible assets are carried at cost less any accumulated amortization and accumulated impairment losses. The amortization expense on intangible assets with finite lives is recognized in the statement of profit or loss in the expense category that is consistent with the function of the intangible assets.

3.2 Grants and donations

Grants related to assets, including non-monetary grants at fair value, are presented in the statement of financial position as deferred income under non-current liabilities and are recognized as income on a systematic and rational basis over the useful life of the asset.

Revenue grants are recognized as income in the year in which they are received and are credited to the statement of comprehensive income.

Donations are recognized as deferred income when used to purchase assets and are amortized over the economic useful life of the assets.

3.3 Taxation

The Subsidiary, Percentage Discount is liable to pay income tax as required by tax laws in Zimbabwe, Income tax Act [*Chapter 23:06*].

i. Current tax

Income tax expenses represent the sum of the tax currently payable and deferred tax. The currently payable tax is based on taxable profit for the year and the Authority is exempted from paying corporate tax. Taxable profit differs from profit as reported in the statement of comprehensive income because it excludes items of income or expense that are taxable or deductible in other years and it further excludes items that are never taxable or deductible. Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted by Zimbabwe Revenue Authority.

ii. Deferred tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date. Deferred tax liabilities are recognized for all taxable temporary differences, except:

- When the deferred tax liability arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss;
- In respect of taxable temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, when the timing of the reversal of the

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
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temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilized, except:

When the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss

- In respect of deductible temporary differences associated with investment in subsidiary, deferred tax assets are recognized only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are reassessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered. In assessing the recoverability of deferred tax assets, the Group relies on the same forecast assumptions used elsewhere in the financial statements and in other management reports. Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date. Deferred tax items are recognized in correlation to the underlying transaction either in Other Comprehensive Income or directly in equity.

3.4 Financial instruments

Financial instruments are contracts that give rise to financial assets or financial liabilities. Financial assets and financial liabilities are recognized on the Group's statement of financial position when the Group becomes a party to the contractual provisions of the instrument. These instruments are generally carried at their estimated carrying values.

Non-derivative financial instruments carried in the statement of financial position comprise: cash and cash equivalents, trade and other receivables, trade and other payables. These instruments are recognized initially at fair value plus any directly attributable transaction costs.

3.4.1 Financial assets

The Authority classified all its financial assets based on the business managing the assets and the asset's contractual terms measured at either;

- Amortised cost
- Fair value through other comprehensive income (FVOCI)

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- Fair value through profit and loss (FVPL)

Financial assets at FVPL	These assets are subsequently measured at fair value. Net gains and losses, including any interest or dividend income, are recognised in profit or loss.	(1) Money market investment. (2) Stock Market shares.
Armotised cost	These are subsequently measured at armotised cost	(1) Loans and advances (2) Mortgage investments

- The Authority measures loans and advances to staff, money market, investments and mortgage investments at amortised cost if both of the following conditions are met.
- The financial asset is held within a business model with the objective to hold financial assets in order to collect contractual cashflows and.
- The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest (SPPI).

3.4.1.1 Cash and cash equivalents

Cash and cash equivalents comprise cash balances and call deposits (funds on placement) with maturities of three months or less from acquisition date that are subject to insignificant risk of changes in fair value, and are used by the Group in the management of its short-term commitments.

3.4.1.2 Trade and other receivables

Trade and other receivables are measured at their cost less impairment losses. A provision for impairment of trade receivables is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of receivables. Significant financial difficulties of the debtor, probability that the debtor will enter bankruptcy or financial reorganization and default or delinquency in payments are considered indicators that the trade receivables are impaired. When a trade receivable is uncollectible, it is written off against the allowance for trade receivables. Subsequent recoveries of amounts previously written off are credited against the trade receivables impairment provision in profit or loss.

3.4.1.3 Impairment

A financial asset not classified at fair value through profit or loss is measured at each reporting date to determine whether there is objective evidence that it is impaired. A financial asset is impaired if there is objective evidence of impairment as a result of one or more events that occurred after the initial recognition of the asset, and that loss events had an impact on the estimated future cash flows of that asset that can be estimated reliably.

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Objective evidence that financial assets are impaired includes default or delinquency by the debtor, restructuring of an amount due to the Group on terms that the Group would not consider otherwise, indications that a debtor will enter bankruptcy, changes in the payment status, and disappearance of an active market for a security.

3.4.1.4 Investment in listed equity shares

The Authority holds equity shares in five (5) counters listed on the stock exchange and these are designated as financial assets at fair value through profit or loss. Fair values of these equity shares are determined by reference to published price quotations in an active market.

3.4.2 Financial liabilities

3.4.2.1 Liabilities and provisions

Liabilities payable after one year from the reporting date are treated as non-current liabilities in the statement of financial position. Provisions are recognized when the Group has a present legal or constructive obligation as a result of past events and a reliable estimate to the amount of such obligation can be made. Obligations payable at the demand of the creditor or within one year of the reporting date are treated as current liabilities in the statement of financial position.

3.5 Inventory

Inventories are valued using the moving average method. Inventory values in the system are determined by the average of the existing inventory value and the price of incoming inventory. Net realizable value represents the estimated selling price for inventories less all estimated costs of completion and costs necessary to make the sale.

During 2023, the Authority added laboratory reagents to its inventory as the value was considered to be material.

3.6 Revenue recognition

The mandate of the Group is to protect public health by ensuring that medicines and medical devices on the market are safe, effective and of good quality. The main revenue lines for the Authority are shown below and these are recognized in accordance with International Financial Reporting Standard 15- "Revenue from contracts with customer" five-step model.

i. Permits/licenses fees

Permits/Licenses fees are recognized at a point in time when the permits or licenses have been issued.

ii. Registration fees

Registration fees are recognized at a point in time when the customer has been issued with a registration certificate.

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iii. Renewal fees

License Renewal fees are recognized at a point in time when the customer has been issued with a renewal certificate.

iv. Retention fees

Retention fees are recognized at a point in time when the customer has been issued with a retention statement.

v. GMP inspection fees

GMP inspection fees are recognized at a point in time when the GMP inspection has been conducted.

vi. Laboratory income

Laboratory income is recognized at a point in time when the sample tests have been conducted.

3.7 Pension arrangement

The MCAZ Defined Contribution Scheme is a long term savings plan whereby both the employer and employee contribute fixed monthly pension premiums to a savings account.

i. MCAZ Defined Contribution Scheme

The employer is obliged to pay 15% of the monthly basic salary of the employee whereas the employee contributes 7.5% towards the same scheme to bring the monthly total contribution for each employee to 22.5% monthly. Each year interest is earned through investment of the contributions and is credited into members' accounts. The benefit at retirement is dependent on the contributions paid into the account and interest earned. So, the final pension benefit is not directly related to one's salary and service of member upon retirement. The Fund was set up on the 1st of May 1998 as self-insured and is administered by ZIMNAT Life Assurance Company. Obligations for contributions to defined contribution plans are recognized as an employee benefit expense in profit or loss in the period during which related services are rendered by employees.

ii. NSSA Scheme

The NSSA Scheme is compulsory or mandatory social security scheme for all registered businesses and was set up by the Government of Zimbabwe back in 1994. It operates two schemes i.e. pension and other benefits scheme as well as the accident prevention and worker's compensation scheme. The objective of NSSA is to provide social security to workers in situations of sickness, workplace injuries, unemployment, invalidity, old age, retirement, ill-health and death. It therefore, draws savings from periods of employment, earnings, etc. to meet the social security needs of workers. Contributory rates are determined based on monthly income with a minimum of 3% of an employee's monthly earnings the same rate for the employer up to a given ceiling. Obligations for contributions to the NSSA scheme are recognized as an employee benefit expense in profit or loss in the period during which related services are rendered by employees.

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MCAZ GROUP		Freehold land		Buildings		Plant and machinery		Motor vehicles		Computer and equipment		Office equipment		Furniture and fittings		Work in progress		Total		
		ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$
4. Property, plant and equipment																				
Inflation adjusted																				
Opening carrying amount		4 724 451 060	8 839 972 041	1 644 978 562	774 747 291	634 419 318	130 259 159	298 378 863	5 172 331	17 052 378 625	10 237 374 197									
Gross carrying amount		4 724 451 060	9 638 483 101	2 506 170 944	1 326 050 715	1 493 632 020	354 126 818	458 327 865	5 172 331	20 506 414 854	12 725 779 929									
Accumulated depreciation		-	(798 511 060)	(861 192 382)	(551 303 424)	(859 212 702)	(223 867 659)	(159 949 002)	-	(3 454 036 229)	(2 488 405 732)									
Additions at cost		-	-	5 790 100 883	811 196 388	334 773 365	131 456 057	351 820 242	-	7 419 346 935	375 077 478									
Work in progress completed and transferred		-	-	5 172 331	-	-	-	-	(5 172 331)	-	-									
Asset classified as held for sale		-	-	-	(33 829 830)	-	-	-	-	(33 829 830)	-									
Gross carrying amount		-	-	-	(612 492 711)	-	-	-	-	(612 492 711)	-									
Accumulated depreciation		-	-	-	578 662 881	-	-	-	-	578 662 881	-									
Revaluation surplus		5 829 573 940	8 968 282 678	-	-	-	-	-	-	-	7 491 906 741									
Gross carrying amount		5 829 573 940	12 253 767 815	-	-	-	-	-	-	-	18 083 341 755									
Accumulated depreciation		-	(3 285 485 137)	-	-	-	-	-	-	-	(3 285 485 137)									
Disposals carrying amount		-	-	-	-	(1 027 292)	-	-	-	(1 027 292)	(60 492 829)									
Disposals at cost		-	-	-	-	(2 352 634)	-	-	-	(2 352 634)	(86 349 295)									
Accumulated depreciation		-	-	-	-	1 325 342	-	-	-	1 325 342	25 856 466									
Depreciation charge for the year		-	(354 779 718)	(397 576 428)	(313 843 364)	(122 911 701)	(54 473 743)	(48 066 338)	-	(1 291 651 292)	(991 486 962)									
Closing carrying amount		10 554 025 000	17 453 475 001	7 042 675 348	1 238 270 485	845 253 690	207 241 473	602 132 767	-	37 943 073 764	17 052 378 625									
Gross carrying amount		10 554 025 000	21 892 250 916	8 301 444 158	1 524 754 392	1 826 032 751	485 582 875	810 148 107	-	45 394 258 199	20 506 414 853									
Accumulated depreciation		-	(4 438 775 915)	(1 258 768 810)	(286 483 907)	(980 799 051)	(278 341 402)	(208 015 340)	-	(7 451 184 435)	(3 454 036 228)									
Historical cost																				
Opening carrying amount		983 160 000	1 839 600 891	342 065 691	161 225 220	132 022 894	27 106 979	62 092 751	1 076 364	602 863 484	921 348 006									
Gross carrying amount		983 160 000	2 309 469 031	1 226 808 553	1 185 394 177	62 028 335 314	3 236 930 896	232 440 286	1 076 364	71 203 614 621	921 348 006									
Accumulated depreciation		-	(469 868 140)	(884 752 862)	(1 024 168 957)	(61 896 312 420)	(3 209 823 917)	(170 347 535)	-	(67 655 273 831)	(318 484 522)									
Additions at cost		-	-	4 642 152 019	447 938 606	173 544 142	56 425 681	187 647 648	-	5 507 706 096	108 274 213									
Work in progress completed and transferred		-	-	1 076 364	-	-	-	-	(1 076 364)	-	-									
Asset classified as held for sale		-	-	-	(7 040 000)	-	-	-	-	(7 040 000)	-									
Gross carrying amount		-	-	-	(127 459 958)	-	-	-	-	(127 459 958)	-									
Accumulated depreciation		-	-	-	120 419 958	-	-	-	-	120 419 958	-									
Revaluation surplus		9 570 865 000	15 717 835 988	-	-	-	-	-	-	-	2 877 761 367									
Gross carrying amount		9 570 865 000	20 668 655 250	-	-	-	-	-	-	-	30 239 520 250									
Accumulated depreciation		-	(4 950 819 262)	-	-	-	-	-	-	-	(4 950 819 262)									
Disposals carrying amount		-	-	-	-	(1 027 292)	-	-	-	(1 027 292)	(3 741 165)									
Disposals at cost		-	-	-	-	(2 352 634)	-	-	-	(2 352 634)	(8 125 912)									
Accumulated depreciation		-	-	-	-	1 325 342	-	-	-	1 325 342	4 384 747									
Depreciation charge for the year		-	(103 961 878)	(147 082 025)	(72 514 064)	(49 930 753)	(14 520 345)	(15 274 263)	-	(403 283 328)	(36 817 109)									
Closing carrying amount		10 554 025 000	17 453 475 001	4 838 202 049	529 609 762	254 608 991	69 012 315	234 466 136	-	33 933 395 254	3 548 340 790									
Gross carrying amount		10 554 025 000	22 978 124 281	5 870 036 936	1 505 872 825	62 199 526 822	3 293 356 577	420 087 934	-	106 821 030 375	71 203 614 621									
Accumulated depreciation		-	(5 524 649 280)	(1 031 834 887)	(976 263 063)	(61 944 917 831)	(3 224 344 262)	(185 621 798)	-	(72 887 631 121)	(67 655 273 831)									

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AUTHORITY (continued)	Freehold land	Buildings	Plant and machinery	Motor vehicles	Computer and equipment	Office equipment	Furniture and fittings	Work in progress	Total 2022
4 Property, plant and equipment	ZWLS	ZWLS	ZWLS	ZWLS	ZWLS	ZWLS	ZWLS	ZWLS	ZWLS
4 Property, plant and equipment									
Inflation adjusted									
Opening carrying amount	3 672 266 486	7 230 165 036	1 643 691 990	774 747 407	634 419 318	130 259 159	288 378 863	5 172 331	14 389 100 572
Gross carrying amount	3 672 266 488	7 841 037 748	2 503 951 111	1 326 050 826	1 493 632 020	354 126 818	458 327 865	5 172 331	11 707 539 675
Accumulated depreciation	-	(710 872 710)	(860 259 121)	(551 303 419)	(859 212 702)	(223 867 659)	(159 949 002)	-	(3 365 464 613)
Additions at cost	-	-	5 790 100 883	811 196 388	334 773 365	131 456 057	351 820 242	-	7 419 346 935
Work in progress completed-reclassified	-	-	5 172 331	-	-	-	-	(5 172 331)	-
Asset classified as held for sale	-	-	-	(33 829 830)	-	-	-	-	(33 829 830)
Gross carrying amount	-	-	-	(612 492 711)	-	-	-	-	(612 492 711)
Accumulated depreciation	-	-	-	578 662 881	-	-	-	-	578 662 881
Revaluation surplus	4 454 158 533	9 006 664 090	-	-	-	-	-	-	13 460 822 623
Gross carrying amount	4 454 158 533	12 292 149 227	-	-	-	-	-	-	16 746 307 760
Accumulated depreciation	-	(3285 485 137)	-	-	-	-	-	-	(3 285 485 137)
Disposals carrying amount	-	-	-	-	(1 027 292)	-	-	-	(1 027 292)
Gross carrying amount	-	-	-	-	(2 352 634)	-	-	-	(86 349 295)
Accumulated depreciation	-	-	-	-	1 325 342	-	-	-	1 325 342
Depreciation charge for the year	-	(180 754 126)	(397 354 445)	(313 843 364)	(122 911 701)	(54 473 743)	(48 066 338)	-	(1 117 403 717)
Closing carrying amount	8 126 425 001	16 056 075 000	7 041 610 759	1 238 270 601	845 253 690	207 241 473	602 132 767	-	34 117 009 291
Gross carrying amount	8 126 425 001	20 233 186 973	8 299 224 325	1 524 754 503	1 826 052 751	485 582 875	810 148 107	-	41 305 374 535
Accumulated depreciation	-	(4 177 111 973)	(1 257 613 566)	(286 483 902)	(980 799 051)	(278 341 402)	(208 015 340)	-	(7 188 365 244)
Historical cost									
Opening carrying amount	764 200 001	1 504 600 000	342 052 907	161 225 220	132 022 894	27 105 979	62 092 751	1 076 364	2 994 377 116
Gross carrying amount	764 200 001	1 965 299 871	1 226 603 488	1 185 394 177	62 028 335 314	3 236 930 896	232 440 286	1 076 364	70 640 480 397
Accumulated depreciation	-	(460 699 871)	(884 750 581)	(1 024 168 957)	(61 896 312 420)	(3 209 823 917)	(170 347 535)	-	(67 646 103 281)
Additions at cost:	-	-	4 642 152 019	447 938 606	173 544 142	56 425 681	187 647 648	-	5 507 708 096
Work in progress completed-reclassified	-	-	1 076 364	-	-	-	-	(1 076 364)	-
Asset classified as held for sale	-	-	-	(7 040 000)	-	-	-	-	(7 040 000)
Gross carrying amount	-	-	-	(127 459 958)	-	-	-	-	(127 459 958)
Accumulated depreciation	-	-	-	120 419 958	-	-	-	-	120 419 958
Revaluation surplus	7 362 225 000	14 588 090 000	-	-	-	-	-	-	21 951 315 000
Gross carrying amount	7 362 225 000	19 539 909 262	-	-	-	-	-	-	26 902 134 262
Accumulated depreciation	-	(4 950 819 262)	-	-	-	-	-	-	(4 950 819 262)
Disposals carrying amount	-	-	-	-	(1 027 292)	-	-	-	(1 027 292)
Gross carrying amount	-	-	-	-	(2 352 634)	-	-	-	(8 125 912)
Accumulated depreciation	-	-	-	-	1 325 342	-	-	-	1 325 342
Depreciation charge for the year	-	(37 615 000)	(147 081 518)	(72 514 064)	(49 930 753)	(14 520 345)	(15 274 263)	-	(33 693 5943)
Closing carrying amount	8 126 425 001	16 056 075 000	4 838 199 772	529 609 762	254 608 991	69 012 315	234 466 136	-	30 108 396 977
Gross carrying amount	8 126 425 001	21 505 206 133	5 870 031 871	1 506 672 825	62 199 526 822	3 293 356 577	420 087 934	-	102 920 510 163
Accumulated depreciation	-	(5 449 134 133)	(1 031 832 099)	(976 263 063)	(61 944 917 831)	(322 434 262)	(185 621 798)	-	(72 812 113 186)

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	MCAZ GROUP				AUTHORITY			
	Inflation adjusted 2023 ZWL\$	Historical cost 2023 ZWL\$	2022 ZWL\$	Historical cost 2022 ZWL\$	Inflation adjusted 2023 ZWL\$	2022 ZWL\$	Historical cost 2023 ZWL\$	Historical cost 2022 ZWL\$
5 Investment property								
Opening fair value	5 093 695 958	1 060 000 000	202 501 100	202 501 100	5 093 695 958	3 345 104 382	1 060 000 000	202 501 100
Fair value adjustment	6 381 304 042	10 415 000 000	857 488 900	857 488 900	6 381 304 042	1 748 591 576	10 415 000 000	857 488 900
Closing value	11 475 000 000	11 475 000 000	1 060 000 000	1 060 000 000	11 475 000 000	5 093 695 958	11 475 000 000	1 060 000 000
6 Investment in subsidiary								
Percentage Discount (Private) Limited	-	-	-	-	882 193 238	882 193 238	218 595	218 595
	-	-	-	-	882 193 238	882 193 238	218 595	218 595
7 Other long term financial assets								
Equity shares	21 917 293	21 917 293	-	21 917 293	21 917 293	-	21 917 293	-
	21 917 293	21 917 293	-	21 917 293	21 917 293	-	21 917 293	-
Equity shares purchases	21 917 293	21 917 293	-	21 917 293	21 917 293	-	21 917 293	-
Equity share valuation at December 31, 2023	(3 960 919)	(3 960 919)	-	(3 960 919)	(3 960 919)	-	(3 960 919)	-
Fair value adjustments	17 956 375	17 956 375	-	17 956 375	17 956 375	-	17 956 375	-
8 Inventory								
Fuel	86 599 486	18 386 563	5 688 358	5 688 358	86 599 486	27 382 739	18 386 563	5 688 358
Staff provisions	196 623 955	19 786 918	1 921 337	1 921 337	196 623 955	19 786 918	41 445 065	1 921 337
Stationery consumables	238 410 523	154 832 452	7 614 226	7 614 226	238 410 523	537 550 872	154 832 452	7 614 226
Laboratory consumables	348 124 634	111 348 038	-	111 348 038	348 124 634	-	111 348 038	-
	869 758 578	326 012 138	15 233 921	15 233 921	869 758 578	584 720 529	326 012 138	15 233 921
9 Trade and other receivables								
Trade receivables	1 611 263 501	1 611 263 501	167 269 811	167 269 811	1 611 263 501	803 793 925	1 611 263 501	167 269 811
Allowance for credit losses	(129 223 257)	(129 223 257)	(17 371 622)	(17 371 622)	(129 223 257)	(63 478 094)	(17 371 622)	(17 371 622)
	1 482 040 244	1 482 040 244	149 897 989	149 897 989	1 482 040 244	720 315 831	1 482 040 244	149 897 989
Staff receivables	747 449 200	747 449 200	123 558 624	123 558 624	747 449 200	593 745 343	747 449 200	123 558 624
Related party receivables	2 229 489 444	2 229 489 444	273 456 613	273 456 613	2 229 489 444	1 338 754 480	2 229 489 444	273 456 613
	14 197 739	16 222 585	3 375 926	3 375 926	-	-	-	-
Tax receivable	2 243 687 183	2 243 687 183	276 832 539	276 832 539	2 229 489 444	1 338 754 480	2 229 489 444	276 832 539
10 Prepayments								
Bank	1 021 940 460	663 685 249	69 556 662	69 556 662	1 021 940 460	334 245 743	663 685 249	69 556 662
	1 021 940 460	1 021 940 460	69 556 662	69 556 662	1 021 940 460	334 245 743	663 685 249	69 556 662
11 Cash and cash equivalents								
Bank	17 809 176 702	17 809 176 702	2 808 336 708	2 808 336 708	17 512 074 770	13 290 684 213	17 512 074 770	2 765 796 267
Funds on placement	3 080 054 758	3 080 054 758	990	990	3 080 054 758	4 757	3 080 054 758	990
	20 889 231 460	20 889 231 460	2 808 337 698	2 808 337 698	20 592 129 528	13 290 688 970	20 592 129 528	2 765 797 257
12 Non current asset held for sale								
	7 040 000	7 040 000	-	-	7 040 000	-	7 040 000	-
	7 040 000	7 040 000	-	-	7 040 000	-	7 040 000	-
13 Deferred income								
Opening carrying amount	1 981 646 092	13 640 999	15 688 367	15 688 367	1 981 646 092	1 981 646 092	13 640 999	15 688 367
Balance as at January 1	2 219 466 584	17 333 735	17 333 735	17 333 735	2 219 466 584	2 219 466 584	17 333 735	17 333 735
Accumulated amortisation	(237 820 492)	(3 692 736)	(1 645 368)	(1 645 368)	(237 820 492)	(219 953 080)	(3 692 736)	(1 645 368)
	(9 158 331)	(17 867 412)	(2 047 368)	(2 047 368)	(9 158 331)	(17 867 412)	(1 905 652)	(2 047 368)
Closing carrying amount	1 972 487 761	13 640 999	13 640 999	13 640 999	1 972 487 761	1 981 646 092	11 735 147	13 640 999
Balance as at December 31	(246 978 823)	(237 820 492)	(3 692 736)	(3 692 736)	(246 978 823)	(237 820 492)	(5 598 585)	(3 692 736)
Accumulated amortisation	1 972 487 761	1 981 646 094	11 735 147	11 735 147	1 972 487 761	1 981 646 092	11 735 148	13 640 999
Non-current	1 970 624 745	1 972 487 763	9 672 131	9 672 131	1 959 345 078	1 972 487 761	9 672 132	11 735 147
Amortisation charge due next year	1 863 016	1 863 016	1 905 652	1 905 652	313 142 685	9 158 331	1 863 016	1 905 652

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	Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	2023 ZWL\$	2022 ZWL\$	2023 ZWL\$	2022 ZWL\$	2023 ZWL\$	2022 ZWL\$	2023 ZWL\$	2022 ZWL\$
14 Income tax expense								
Current tax	10 500 893	6 047 928	10 500 893	1 258 576	-	-	-	-
Deferred tax	10 500 893	6 047 928	10 500 893	1 258 576	-	-	-	-
14.1 Tax reconciliation								
Profit before tax	42 479 340	24 465 728	42 479 340	5 091 327	-	-	-	-
National tax thereon at a rate of 24.72%	10 500 893	6 047 928	10 500 893	1 258 576	-	-	-	-
Permanent differences	10 500 893	6 047 928	10 500 893	1 258 576	-	-	-	-
14.2 Current tax liability/asset								
Balance as at January 1, 2022	(16 222 585)	(3 375 926)	(3 375 926)	(75 538)	-	-	-	-
Current year charge	10 500 893	6 047 928	10 500 893	1 258 576	-	-	-	-
Payments	(32 801 485)	(21 907 525)	(21 322 706)	(4 558 964)	-	-	-	-
Effects of inflation	24 325 438	-	-	-	-	-	-	-
Balance as at December 31, 2023	(14 197 739)	(14 197 739)	(14 197 739)	(3 375 926)	-	-	-	-
14.3 Deferred tax								
Balance at January 1, 2023	684 296 452	233 914 102	147 997 498	14 160 350	-	-	-	-
Deferred tax recognised through other comprehensive income	330 514 701	101 879 635	825 001 817	81 090 398	-	-	-	-
Deferred tax recognised directly in equity	-	348 502 715	52 746 750	-	-	-	-	-
Net deferred tax liability	1 014 811 153	684 296 452	972 999 315	147 997 498	-	-	-	-
15 Trade and other payables								
Trade payables	573 477 310	445 348 306	573 477 310	92 677 146	573 477 310	445 348 306	573 477 310	92 677 146
Sundry payables	652 611 989	302 303 570	652 611 989	62 908 484	652 611 989	279 609 694	652 611 989	58 186 880
Related party payables	-	-	-	90 697 364	-	-	-	-
Other payables	6 019 563 511	1 523 986 901	6 019 563 511	317 142 234	6 017 413 014	1 523 437 777	6 017 413 014	317 027 961
Unallocated income	110 250 306	39 298 330	110 250 306	8 177 997	110 250 306	39 298 330	110 250 306	8 177 997
	7 355 903 116	2 310 937 107	7 355 903 116	480 908 861	7 444 449 983	2 287 694 107	7 444 449 983	476 069 984
16 Provisions								
Leave pay provision	84 681 753	48 796 132	84 681 753	10 154 493	84 681 753	48 796 132	84 681 753	10 154 493
	84 681 753	48 796 132	84 681 753	10 154 493	84 681 753	48 796 132	84 681 753	10 154 493
17 Medicines control income								
Amendment fees	1 622 702 213	350 061 641	649 916 363	50 756 315	1 622 702 213	350 061 641	649 916 363	50 756 315
Clinical trials	193 390 100	97 421 793	140 666 313	15 289 746	193 390 100	97 421 793	140 666 313	15 289 746
Dangerous drugs license	599 424 751	366 735 782	379 237 404	41 290 592	599 424 751	366 735 782	379 237 404	41 290 592
Drug registration and forensic examination	46 085 922	17 405 318	29 824 998	2 729 228	46 085 922	17 405 318	29 824 998	2 729 228
Import and export licenses	6 971 397 585	1 733 193 048	4 616 890 526	252 166 530	6 971 397 585	1 733 193 048	4 616 890 526	252 166 530
Inspection	5 544 253 445	1 733 058 296	3 338 862 862	262 474 172	5 544 253 445	1 733 058 296	3 338 862 862	262 474 172
Persons and premises licenses	1 952 724 142	694 746 952	1 062 507 720	96 483 866	1 952 724 142	694 746 952	1 062 507 720	96 483 866
Registration fees	6 837 944 470	1 999 737 412	4 091 916 672	275 784 756	6 837 944 470	1 999 737 412	4 091 916 672	275 784 756
Renewal of licenses	3 030 691 750	1 269 890 656	856 598 552	100 810 721	3 030 691 750	1 269 890 656	856 598 552	100 810 721
Retention fees	6 726 327 163	2 599 253 571	4 287 926 760	381 946 462	6 726 327 163	2 599 253 571	4 287 926 760	381 946 462
Sales representatives and wholesale dealers	670 328 255	137 866 639	340 131 509	18 430 493	670 328 255	137 866 639	340 131 509	18 430 493
Unregistered medicines	2 266 306 386	483 430 165	1 247 648 697	74 961 254	2 266 306 386	483 430 165	1 247 648 697	74 961 254
Veterinary permits	394 160 342	98 204 478	142 702 941	10 124 621	394 160 342	98 204 478	142 702 941	10 124 621
	36 855 736 524	11 580 525 751	21 184 831 317	1 583 248 756	36 855 736 524	11 580 525 751	21 184 831 317	1 583 248 756
18 Laboratory services income								
Condom testing	585 799 476	373 807 471	450 572 431	60 945 285	585 799 476	373 807 471	450 572 431	60 945 285
Glove testing	60 841 261	64 480 823	40 192 519	9 852 428	60 841 261	64 480 823	40 192 519	9 852 428
Samples - external clients	5 347 280 870	2 135 861 530	3 747 721 972	336 497 581	5 347 280 870	2 135 861 530	3 747 721 972	336 497 581
	5 993 921 607	2 574 149 824	4 238 486 922	407 285 294	5 993 921 607	2 574 149 824	4 238 486 922	407 285 294

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
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for the year ended December 31, 2023

	MCAZ GROUP						AUTHORITY					
	Inflation adjusted		Historical cost		Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	2023 ZWLS	2022 ZWLS	2023 ZWLS	2022 ZWLS	2023 ZWLS	2022 ZWLS	2023 ZWLS	2022 ZWLS	2023 ZWLS	2022 ZWLS	2023 ZWLS	2022 ZWLS
19 Other income												
Amortisation for the year	9 158 331	17 867 412	1 905 852	2 047 368	9 158 331	17 867 412	1 905 852	2 047 368	9 158 331	17 867 412	1 905 852	2 047 368
Dividend received	-	-	-	-	16 404 990	-	-	-	16 404 990	-	11 489 954	-
Donations	1 239 065 991	405 083 461	743 856 453	68 438 128	1 239 065 991	405 083 461	743 856 453	68 438 128	1 239 065 991	405 083 461	743 856 453	68 438 128
Interest earned	631 331 642	25 582 925	580 203 272	4 534 870	631 331 642	25 582 925	580 203 272	4 534 870	631 331 642	25 582 925	580 203 272	4 534 870
Rentals	688 464 667	435 759 846	378 326 258	64 571 861	666 377 494	329 622 729	378 326 258	64 571 861	666 377 494	329 622 729	378 326 258	64 571 861
Fair value adjustment- investment property	6 381 304 042	1 748 591 575	10 415 000 000	857 498 900	6 381 304 042	1 748 591 575	10 415 000 000	857 498 900	6 381 304 042	1 748 591 575	10 415 000 000	857 498 900
Fair value adjustment- Equity shares	3 960 918	-	3 960 918	-	3 960 918	-	3 960 918	-	3 960 918	-	3 960 918	-
Sundry income	230 714 274	292 319 763	110 153 029	39 843 459	230 714 274	292 319 763	110 153 029	39 843 459	230 714 274	292 319 763	110 153 029	39 843 459
Exchange gain/loss realised	-	5 454 176 086	-	-	-	5 454 176 086	-	-	-	5 454 176 086	-	-
Exchange gain/loss unrealised	49 190 128 227	5 224 797 668	17 457 371 924	1 068 474 724	49 190 128 227	5 224 797 668	17 457 371 924	1 068 474 724	49 190 128 227	5 224 797 668	17 457 371 924	1 068 474 724
Decrease in provision for credit losses	325 329 065	-	3 275 243	-	325 329 065	-	3 275 243	-	325 329 065	-	3 275 243	-
	58 374 128 092	13 929 507 801	29 690 777 706	3 224 546 848	58 031 629 939	13 989 937 137	29 365 450 471	3 180 667 403	58 031 629 939	13 989 937 137	29 365 450 471	3 180 667 403
20 Administration expenses												
Audit fees	89 967 128	38 035 935	19 213 656	3 856 753	89 967 128	38 035 935	19 213 656	3 856 753	89 967 128	38 035 935	19 213 656	3 856 753
Board fees	884 543 388	269 033 663	545 004 543	46 710 711	884 543 388	269 033 663	545 004 543	46 710 711	884 543 388	269 033 663	545 004 543	46 710 711
Bank charges	779 210 344	394 299 625	443 819 413	64 566 709	779 210 344	394 299 625	443 819 413	64 566 709	779 210 344	394 299 625	443 819 413	64 566 709
Communications	197 332 324	56 671 673	132 820 834	8 852 694	197 332 324	56 671 673	132 820 834	8 852 694	197 332 324	56 671 673	132 820 834	8 852 694
Consumables	618 748 917	67 916 656	330 112 731	11 420 144	618 748 917	67 916 656	330 112 731	11 420 144	618 748 917	67 916 656	330 112 731	11 420 144
Depreciation charge for the year	1 291 651 292	991 486 962	403 283 328	36 817 109	1 291 651 292	991 486 962	403 283 328	36 817 109	1 291 651 292	991 486 962	403 283 328	36 817 109
General administration	2 385 982 655	873 880 005	1 479 889 789	140 473 719	2 385 982 655	873 880 005	1 479 889 789	140 473 719	2 385 982 655	873 880 005	1 479 889 789	140 473 719
Increase in provision for leave pay	328 688 877	30 276 222	74 527 260	6 300 492	328 688 877	30 276 222	74 527 260	6 300 492	328 688 877	30 276 222	74 527 260	6 300 492
Increase in provision for credit losses	111 851 435	-	111 851 435	-	111 851 435	-	111 851 435	-	111 851 435	-	111 851 435	-
Foreign exchange loss- released	8 290 194 392	-	2 905 283 844	-	8 290 194 392	-	2 905 283 844	-	8 290 194 392	-	2 905 283 844	-
Inspections	2 758 531 249	860 012 941	1 600 781 468	129 877 035	2 758 531 249	860 012 941	1 600 781 468	129 877 035	2 758 531 249	860 012 941	1 600 781 468	129 877 035
IT expenses	1 030 101 772	382 881 020	552 762 922	65 129 093	1 030 101 772	382 881 020	552 762 922	65 129 093	1 030 101 772	382 881 020	552 762 922	65 129 093
Legal and professional fees	310 691 570	94 489 843	179 898 064	12 100 897	310 691 570	94 489 843	179 898 064	12 100 897	310 691 570	94 489 843	179 898 064	12 100 897
Printing and stationery	552 551 311	174 052 009	343 729 872	27 632 594	552 551 311	174 052 009	343 729 872	27 632 594	552 551 311	174 052 009	343 729 872	27 632 594
Loss on disposal of property, plant and equipment	1 167 626	49 168 678	1 027 292	3 564 649	1 167 626	49 168 678	1 027 292	3 564 649	1 167 626	49 168 678	1 027 292	3 564 649
Public relations	319 999 373	133 597 410	161 183 616	24 169 780	319 999 373	133 597 410	161 183 616	24 169 780	319 999 373	133 597 410	161 183 616	24 169 780
Quality assurance costs	18 837 914	8 970 080	14 722 834	1 820 387	18 837 914	8 970 080	14 722 834	1 820 387	18 837 914	8 970 080	14 722 834	1 820 387
Rates, electricity and water	218 977 583	91 589 199	122 744 289	14 786 685	218 977 583	91 589 199	122 744 289	14 786 685	218 977 583	91 589 199	122 744 289	14 786 685
Repairs and maintenance	2 051 546 284	365 260 384	832 799 584	55 174 488	2 051 546 284	365 260 384	832 799 584	55 174 488	2 051 546 284	365 260 384	832 799 584	55 174 488
Security and insurance costs	219 068 256	130 460 125	115 942 479	21 486 562	219 068 256	130 460 125	115 942 479	21 486 562	219 068 256	130 460 125	115 942 479	21 486 562
Strategic planning	2 805 103 520	443 444 652	1 928 155 135	83 084 850	2 805 103 520	443 444 652	1 928 155 135	83 084 850	2 805 103 520	443 444 652	1 928 155 135	83 084 850
Subscriptions	161 619 215	91 015 385	83 015 605	13 512 005	161 619 215	91 015 385	83 015 605	13 512 005	161 619 215	91 015 385	83 015 605	13 512 005
Travelling and subsistence	60 858 914	58 959 737	13 028 308	9 677 880	60 858 914	58 959 737	13 028 308	9 677 880	60 858 914	58 959 737	13 028 308	9 677 880
Vehicle running costs	264 197 997	174 121 274	132 892 885	25 173 134	264 197 997	174 121 274	132 892 885	25 173 134	264 197 997	174 121 274	132 892 885	25 173 134
	25 751 423 326	5 779 623 478	12 528 491 186	806 188 370	25 361 690 488	5 677 168 926	12 513 222 085	786 930 204	25 361 690 488	5 677 168 926	12 513 222 085	786 930 204

MEDICINES CONTROL AUTHORITY OF ZIMBABWE
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
for the year ended December 31, 2023

	MCAZ GROUP						AUTHORITY		
	Inflation adjusted		Historical cost		Inflation adjusted		Historical cost		
	2023	2022	2023	2022	2023	2022	2023	2022	2022
	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$	ZWL\$
21 Other expenses									
Salaries and wages	18 431 495 307	7 079 204 941	11 144 291 430	1 056 600 513	18 431 495 307	7 079 204 942	11 144 291 430	1 056 600 513	
Pension and medical aid	1 927 641 680	843 097 109	1 104 510 359	119 786 286	1 927 641 680	843 097 109	1 104 510 359	119 786 286	
Staff training expenses	424 747 418	181 488 930	227 773 071	29 198 943	424 747 418	181 488 930	227 773 071	29 198 943	
Staff welfare	761 322 699	146 942 360	551 177 798	25 040 323	761 322 699	146 942 360	551 177 798	25 040 323	
	21 545 207 104	8 250 733 340	13 027 752 658	1 230 626 065	21 545 207 104	8 250 733 341	13 027 752 658	1 230 626 065	
22 Related party transactions									
The remuneration of the Board members and other key management personnel during the financial year were as follows:									
22.1 Board members benefits	211 514 177	40 665 411	120 696 966	6 722 186	201 168 150	40 124 648	120 696 966	6 722 186	
Board members fees	673 029 211	228 368 252	424 307 577	39 988 525	670 285 681	212 994 266	415 961 867	37 369 048	
	884 543 388	269 033 663	545 004 543	46 710 711	871 453 831	253 118 914	536 658 833	44 091 234	
22.2 Key management staff									
Remuneration of key management staff of the Authority comprise of annual basic salary annual bonus, social security contributions, pension and medical aid contributions	107 399 363	45 367 109	29 880 009	2 251 453	107 399 363	45 367 109	29 880 009	2 251 453	
Director-General benefits	444 214 986	235 667 287	253 051 423	35 689 740	444 214 986	235 667 287	253 051 423	35 689 740	
Director-General salary	551 614 349	281 034 396	282 931 432	37 941 193	551 614 349	281 034 396	282 931 432	37 941 193	
23 Contingent Liability									
A court case was instituted against Medicines Control Authority of Zimbabwe during 2023. It was in respect of cancellation of registration for a medical product in the MCAZ Medicines Register following a trademark dispute between two manufacturers. A judgment was passed on March 18, 2024 in which the cancellation of the medicine in the MCAZ register was set aside by the Administrative Court and the product's registration was reinstated. It is not clear when the matter will be finalized.									
24 Events after Reporting Period									
The Government of Zimbabwe introduced a new currency called Zimbabwe Gold (ZIG) to replace the local currency ZWL\$ with effect from April 5, 2024. The opening balances for 2024 as well as balances for the period January to April 4, 2024 will be converted to ZIG to align with the new reporting currency.									



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