MCAZ

Medicines Control Authority of Zimbabwe

Protecting Your right to quality medicines and medical devices

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Abbreviations

ADR	Adverse Drug Reaction
AHF	Aids Healthcare Foundation
AMA	African Medicines Agency
AEFI	Adverse Event Following Immunisation
AHF	Aids Healthcare Foundation
ARVs	Anti-Retrovirals
AVAREF	African Vaccines Regulatory Forum
CGF	Corporate Governance Framework
CHAI	Clinton Health Access Initiative
CTD	Common Technical Document
CSR	Corporate Social Responsibility
e-LMIS	electronic Logistic Management Information System
ERM	Enterprise Risk Management
FHI	Family Health International
GBT	Global Benchmarking Tool
GCP	Good Clinical Practices
GBT	Global Benchmarking Tool
GMP	Good Manufacturing Practices
ICSR	Individual Case Safety Report
ICT	Information Communication Technology
IFRS	International Financial Reporting Standards
MASCA	Medicines and Allied Substances Control Act
MCAZ	Medicines Control Authority of Zimbabwe
ML	Maturity Level
MoHCC	Ministry of Health and Child Care
NBSZ	National Blood Service Zimbabwe
NDS1	National Development Strategy 1
NMRAs	National Medicines Regulatory Authorities
OIE	Office International des Epizooties (World Organization for Animal Health)
PCR	Polymerase Chain Reaction
PSH	Population Solutions for Health
PECOGO	Public Entities Corporate Governance Act
PEI	Paul Ehrlich Institute
SADCAS	Southern African Development Community Accreditation Service
ZAMRA	Zambia Medicines Regulatory Authority
ZNFPC	Zimbabwe National Family Planning Council

Overview of MCAZ

VISION

"To be an effective and efficient regulator for medical products and allied substances in Zimbabwe, and a comparative regulator globally."

Key focus 2022

"To attain WHO GBT level 3 by 31 December 2022."

Key focus 2026

"The authority to be fully automated by 31 December 2026."

MISSION

"To ensure access to safe, effective and good quality medical products and allied substances for the protection of public and animal health."

VALUES

Customer Focus
Integrity.
Continuous Improvement
Accountability
Innovation
Teamwork

CREDO

Protecting your right to quality medicines and medical devices.

Chairperson's Statement

The year 2022 was a special year on the calendar of the Medicines Control Authority of Zimbabwe (MCAZ). The year marked the 25th year of the existence of MCAZ as an autonomous National Medicines Regulatory Authority. It gives me great pleasure to present a synopsis of the activities of the Authority in our silver jubilee anniversary year. This year was also significant as it was the first year of the Authority's new five-year strategic plan. It, therefore, set the foundation for the MCAZ for the next five (5) years. I am glad to report that the Authority managed to meet the key targets of the 2022 calendar year. The Authority managed to achieve its goals and execute its mandate despite the challenging operating environment. However, our Global Benchmarking Tool Maturity Level 3 (GBT ML3) strategic goal, was deferred to 2023. This is in line with the recommendations of the World Health Organization (WHO).

In 2022, we had a board comprised of 10 members appointed by the Honourable Minister of Health and Child Care. The Board held four (4) quarterly meetings which were quorate and managed to review all issues brought to its attention. This allowed the Board to exercise its oversight role and provide strategic direction to the Authority. However, in December of 2022, one of the Board members, Mrs Y. Zhou who also chaired the Complementary Medicines and Finance Committees, resigned from the Authority following her promotion to a new post outside the country by her employers. The Authority would like to thank Mrs. Zhou for her immense contribution to the Board, Complementary Medicines, and Finance Committees and wishes her well in her new role. Mr. Richard Rukwata continued to serve as the Acting Director General as we awaited the appointment of a substantive Director General. I want to appreciate Mr. Rukwata and his management team for continuing to steer the Authority towards its vision to become an effective and efficient regulator for medical products and allied substances in Zimbabwe, and a comparative regulator globally. The Authority satisfactorily discharged its functions within the framework of national and institutional governance standards.

The year 2022 was a transition period from the COVID-19 pandemic period. The board held all its scheduled meetings in a hybrid format. The Authority physically held its Annual General Meeting in October 2022 where the audited financial statements and other reports were presented and adopted. The Authority did not record any conflicts of interest for any of the Board members at any of our Board meetings. The Board ratified and adopted all the decisions that had been made by its technical committees. I commend the commitment shown by the Board and committee members in attending all our meetings and providing their relevant expertise in the discharge of the Authority's mandate.

The Authority developed a new five-year strategic plan, and the year 2022 was the first year of its implementation. A strategic review meeting was held in November 2022 to monitor its implementation.

Chairperson's Statement

There was no major deviation in the attainment of set goals and milestones. The Board continued to play its oversight role over the implementation of its strategic plans through the various technical committees. The MCAZ's strategy was anchored on the National Development Strategy 1 (NDS1) and the National Pharmaceutical Policy. I am pleased to report that the Authority continued to play a facilitative role in the provision of safe, quality, and effective medicines.

As we celebrated the 25th anniversary of the Medicines Control Authority of Zimbabwe, we recognized the important role it had played in protecting public health over the years. I look forward to seeing how this vital organization will continue to evolve and adapt to meet new challenges in the future. In 2023, the Authority pursued its strategic goal of attaining the Global Benchmarking Tool Maturity Level 3 (GBT ML 3). I would like to challenge the management and staff of the MCAZ to continue working hard to attain this goal whilst providing excellent service delivery to our stakeholders as we execute our mandate of protecting public and animal health. I would like to thank our line Minister and Ministry staff, my Board, Management, Staff, development partners, and other local and international stakeholders for supporting the Authority's performance in the year 2022.

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M Chiware (Dr.)
Authority Chairperson

Acting Director - General's Statement

It is my pleasure to present to you the 2022 Annual Report. The year was significant to the Authority in two ways. Firstly, the year marked our silver jubilee anniversary. Secondly, it marked the first year of the implementation of our current five-year strategic plan. As we reflect on the period under review, which encompasses the year 2022, I would like to take this opportunity to highlight both the challenges and successes that the Authority has encountered in the year under review.

Business Process

Inspections: The year 2022 witnessed a significant increase in applications for pharmacy licences and veterinary medicines general dealers permits as well as industrial clinic licences. However, there was a decline in licences issued for dispensing medical practitioners. There was also a significant decline in the number of applications for importation of unregistered medicines (Section 75) received and processed for institutions in 2022.

Enforcement: In 2022, fifteen (15) hearings were conducted. Of the hearings conducted, five (5) persons' licenses were cancelled, one (1) premises license was cancelled, six (6) wholesale dealers' permits were revoked, and three (3) final warnings were issued. MCAZ continues to urge licence and permit holders to comply with all laws and regulations as we work together to protect public and animal health.

Registration: The Authority recorded an 11% increase in revenue collected from applications for externally manufactured products and a 235% increase in revenue collected from applications for locally manufactured products in 2022. The increase in revenue collected for locally manufactured product was very encouraging as an indicator that local manufacturers were heeding the call by the government for greater local participation in the local manufacturing of pharmaceutical products.

Out of the two hundred and fifty-six (256) applications for registration of medicines that were assessed in 2022, one hundred and thirty-eight (138) were registered. The online register for approved human medicines is available on MCAZ website, and the register is updated in real-time.

Automation: The Authority continues to invest in technological advancements, capacity building, and stakeholder engagement to strengthen the regulatory framework. By embracing innovation and harnessing digital solutions, we aim to enhance efficiency, transparency, and accessibility in our operations. The strategic goal is to automate all critical operations by 2026.

Human Capital: The Authority continued to experience a high level of staff attrition resulting in the loss of much sought-after skills. This was attributed to by a number of factors as highlighted in the Human

Acting Director - General's Statement

Resources report which is attached. The Authority has made a lot of effort to provide a generally balanced experience from the employee engagement perspective, notwithstanding the personnel attrition. The Authority continued to face challenges with respect to the issue of competitive remuneration. However, the Authority has a robust competence development process in place, which is supported by a performance management system that has steadily improved over the years. As a result, staff members mature and advance through the grading system, becoming highly proficient and attractive not only just to the local Zimbabwean industry, but also to other regulatory authorities both regionally and internationally. Therefore, the Authority finds itself having to compete with significantly motivated external forces for its highly sought-after skills. This has led the Authority to embark on an exercise to benchmark its remuneration structures against other regional NMRAs in order to provide competitive remuneration and better retain its skilled staff.

Cannabis: The Authority established the Cannabis Desk in 2018. The function was established to administer S.I. 62 of 2018 on behalf of the Ministry of Health and Child Care. A total of fifty-nine (59) licences for the production of Cannabis for medicinal and scientific use have been issued to date. Fifty-eight (58) licenses are currently active with fifty-six (56) licenses being for cultivation and production and two (2) licenses being for cultivation and research licenses. The first license was issued in 2019, and in 2022 only two (2) licenses were issued.

The development of the industry has been very slow and by the end of 2022, there had been no exports of cannabis from Zimbabwe to any other country. Most producers are still setting up their facilities.

The Future

Currently, the Authority is converting one of its laboratories into a cannabis testing laboratory as we continue to support the growing medicinal cannabis sector. Work in the Microbiology laboratory is also continuing, and the goal of achieving WHO pre-qualification is within reach.

I would like to thank the Authority Members, Management Team, all Staff members, and all our stakeholders for making 2022 yet another success. We look forward to the future with excitement as we continue to implement the 2022-2026 strategic plan and make the Authority an effective and efficient regulator for medical products and allied substances in Zimbabwe and a comparative regulator globally.

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Richard T Rukwata (Mr.)

Acting Director-General

MCAZ @25

The Medicines Control Authority of Zimbabwe (MCAZ) celebrated its 25th anniversary in 2022. The celebration is time to reflect on the journey of the years gone by and have a strategic outlook for the future.

MCAZ is a statutory body established by an Act of Parliament on the 1st of August 1997. It is the successor to the Drugs Control Council and the Zimbabwe Regional Drugs Control Laboratory. Since its establishment in 1997, the MCAZ has been at the forefront of ensuring that all medicines and medical devices available in Zimbabwe are safe, effective, and of good quality.

Over the years, the MCAZ has achieved significant milestones in its mission to protect public health. One of its most notable achievements is the development and implementation of a robust regulatory framework for medicines and medical devices. This framework ensures that all products are thoroughly evaluated before they are approved for use in Zimbabwe. In recent years, the MCAZ has also been actively involved in responding to public health emergencies such as COVID-19.

Some of the milestones achieved by MCAZ during its 25 years of existence include the following: The Authority was designated a Regional Centre of Regulatory Excellence (RCORE) under the African Medicines Regulatory Harmonisation (AMRH) Initiative of the African Union and the NEPAD Agency in 2014. This offered training services for new and seasoned regulators from national medicines regulatory authorities (NMRAs), regulatory affairs personnel from the pharmaceutical industry and academia. The areas of RCORE designation include Medicines Registration, Pharmacovigilance and Clinical Trials, and Laboratory Testing of medicines.

The Chemistry laboratory was WHO-Prequalified in 2014 and work on the pre-qualification of the Microbiology laboratory is at an advanced stage. This was an assessment by WHO to confirm that the laboratory meets the recommended international norms and standards for the analysis of medical products. The laboratories were first accredited to ISO 17025:2005 in 2010 by South African National Accreditation System (SANAS) and moved to Southern African Development Accreditation System (SADCAS) in 2015 which has been maintained to date.

In 2018, through S.I 62 of 2018, Zimbabwe became the second African country to legalize cannabis for medical and scientific purposes. MCAZ administers the S.I. 62 of 2018 on behalf of the Ministry of Health and Child Care. MCAZ works with various stakeholders to ensure that medicinal Cannabis, is handled effectively and legally throughout the supply chain. This has expanded the scope of the Authority's mandate. The MCAZ plays a critical role in promoting of medicinal cannabis and the

growth of this sector. Currently the MCAZ is in the process of setting up the cannabis laboratory.

The 25-year anniversary also came against the background of the COVID-19 pandemic. MCAZ played a significant role in the National COVID-19 response strategy. The Authority made sure that the country rolled out the national vaccination strategy successfully by issuing emergency use authorizations (EUAs) for COVID-19 vaccines and providing scientific recommendations on COVID-19 therapeutics that the country needed to protect its citizens. The authority worked closely with other government agencies and international organizations to ensure that essential medical supplies were available during the pandemic.

Another key achievement of the MCAZ is its commitment to transparency and accountability. The authority regularly publishes information on its website about approved products, regulatory decisions, and any adverse events reported by patients or healthcare professionals. This helps to build trust with stakeholders and ensures that everyone has access to accurate information about medicines and medical devices.

Furthermore, the MCAZ has been at the forefront of promoting good manufacturing practices in the local pharmaceutical industry. This has been achieved through regulatory oversight and the implementation of international guidelines, which has resulted in better quality medicines for the people of Zimbabwe.

Governance and Risk Report

Introduction

The Board acknowledges responsibility for its role in ensuring integrity of its corporate governance framework as this is critical to the efficient and effective functioning of the Authority. The Authority is governed and controlled in accordance with provisions of the Medicines and Allied Substance Control Act (MASCA) Chapter (15.03), Public Entities Corporate Governance Act (PECOGA) Chapter (10.31), Public Finance Management Act (PFMA) Chapter (22.19) , King Code on Corporate Governance 2009 (King III), Corporate Governance Framework (CGF) for State Enterprises and Parastatals, International Financial Reporting Standards (IFRS) and the MCAZ Board Charter. Corporate governance is an important part of our system as it provides direction of how the Board executes its oversight responsibilities while enabling the Authority to fulfil its responsibilities to its various stakeholders who include the Government of Zimbabwe, Ministry of Health and Child Care (MoHCC), other government institutions, the pharmaceutical industry, customers, suppliers and the general public.

During 2022, the Board and Management attended a Corporate Governance Training Workshop organized by the MoHCC jointly with the Corporate Governance Unit from the Office of President and Cabinet, to get a clearer understanding and appreciation of the key provisions of the Public Entities Corporate Governance Act and the Public Entities Corporate Governance General Regulations. The training was attended by all the parastatals and councils under the Health Ministry and it provided a platform to share ideas, standardize operations and clarify the complementary roles played by the different entities towards fulfillment of the national health agenda.

Role of the Board

The Board is responsible for providing effective leadership and direction to enhance the long-term value of the Authority, for its shareholders and stakeholders. It 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. Execution of the Board mandate is guided by the Board Charter which outlines the procedures for meetings and responsibilities assigned to Committees and Members.

During the period under review, the Board held four (4) quarterly meetings which were fully quorate, and managed to review all issues brought to its attention. Some of the Board focus areas for 2022 were to implement the strategic plan and review the annual budget before seeking approval from the Ministry, including the timely adoption of the Board Committee and the Director-General's reports.

Governance and Risk Report

Annual General Meeting

The Authority also held its Annual General Meeting on the 31st of October 2022 to approve the 2021 audited Financial Statements. The event gave our principal stakeholders an opportunity to engage directly with the Board members and the then Acting Director-General.

Board Composition

The Board comprised of ten (10) non-executive directors including the Chairman. Members of the Board are appropriately qualified with a diverse range of skills and expertise necessary to drive the Authority forward to meet its objectives. The Members were appointed for a maximum of two four-year terms in accordance with the PECOGA. In December of 2022, one of the Board members, Mrs Y. Zhou who also chaired the Complementary Medicines and Finance Committees resigned from the Authority following her elevation to a new post outside the country. The Authority would like to thank Mrs Zhou for her immense contribution to the Board, Complementary Medicines and Finance Committees and wish her well in her new role.

Board Committees

There are sixteen Committees of the Board which were established to assist it with the effective discharge of its mandate. Whilst the Board retains overall responsibility, the Committees probe issues brought to its attention in greater depth, make recommendations on matters requiring Board approval and report their activities to the Board through their respective Chairpersons. Each of the Committees is chaired by a Board member and includes independent non-executive members who are experts in the relevant field to assist with the technical review of issues brought to the Committees by Management.

Below is a list of the Committees that assisted the Board in discharging its mandate during the period under review. Also included is the attendance record for each of the members for the period January to December 2022: Meetings attended/held

Governance and Risk Report

	Committee	Members	Meetings attended/held	Responsibilities and Achievements
1.	**Authority**	Dr M. Chiware (Chairperson) Dr C Duri Dr S.L Mutambu Dr C. Mutisi Dr. E.O Waniwa Mr P. Mwendera Mr D.N Vuragu Mrs N. Samuriwo Mrs Y .M Zhou Air Commodore P. Zimondi	4/4 4/4 3/4 4/4 4/4 4/4 4/4 3/4 4/4 4/4	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 (Chairperson) Dr C. Pasi Dr R. Chigwanda Dr. E.O Waniwa Dr M. Murwira Mr E. Mupanehari Dr D. Tagwireyi	12/12 8/12 12/12 7/12 12/12 7/12 11/12	Oversight and statutory decision making on registration of medicines
3.	**Laboratory**	Dr S.L Mutambu (Chairperson) Dr E.O Waniwa Prof M Gundidza Mr N. Madzikwa Dr J. Manasa Mrs N.T Mandizha Ms T.G Monera-Penduka Dr M. Murwira	3/4 3/4 4/4 3/4 1/4 4/4 3/4 4/4	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 (Chairperson) Dr E.O Waniwa Dr C. Pasi Mrs J. Chaibva Mr T.A Kureya Director, Epidemiology and Disease Control Dr C.E Ndlovu Dr A. Mushavi Mr N.Madzikwa Ms S Ruzario (Alternate to Mr Kureya) Dr D. Tagwireyi Dr R. Nyikadzino	12/12 7/12 9/12 12/12 1/12 /12 7/12 9/12 7/12 9/12 9/12 11/12	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-mar4keting surveillance.

5.	**Veterinary**	Dr E.O Waniwa (Chairperson) Dr S.L Mutambu Mrs J. Chaibva Dr C.T Hodobo Dr Ndengu Dr P.S Woods Dr F.T Makuvadze	5/6 5/6 6/6 4/6 6/6 5/6 6/6	Oversight and statutory decision making on registration of veterinary medicines
6.	**Licensing**	Dr M. Chiware (Chairperson) Mrs Y.M Zhou Dr A.F Zinanga Mrs M. Mothobi Ms R.C Makunike Mr N. Madzikwa	11/11 9/11 11/11 10/11 11/11 9/11	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
7.	**Audit**	Dr C. Mutisi Air Commodore P. Zimondi Mr D. Mahofa Mrs D. Shinya Adv N. Maphosa	4/4 1/4 4/4 2/4 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.
8.	**Human Resources**	Air Commodore P. Zimondi (Chairperson) Dr C. Duri Mr E. Jinda Mr C. Chiketa Mrs F. Chinogurei Mrs J. Ncube	4/4 4/4 4/4 2/4 2/4 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.
9	**Finance**	Ms Y.M Zhou (Chairperson) Dr M. Chiware Mr I. Ruzengwe Mr C. Shonhiwa Dr A.Z Zinanga	4/4 4/4 3/4 4/4 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.
10.	**Legal Committee and Legal Drafting Sub-Committee**	<u>Legal Committee</u> Mrs N. Samuriwo (Chairperson) Mr P. Mwendera Mrs J. Ncube Mrs J. Chaibva Mr D. Moyo <u>Drafting Sub-Committee</u> Mr P. Mwendera (Chairperson) Dr C. Mutisi Mrs J. Chaibva	 4/7 6/7 6/7 7/7 7/7 1/1 1/1 1/1	 Providing guidance on all legal issues pertaining to the Authority, reviewing and drafting legislation and policies. Reviews legislation

11.	**Complementary Medicines**	Mrs Y . M Zhou (Chairperson) Mr D. Vuragu Mrs TG Monera-Penduka Mr D. Tagwireyi Prof L.S. Chagonda Mr D.T Chagwena Dr T.R Muzamhindo Mr O. Ndoro	4/6 3/6 3/6 4/6 6/6 2/6 6/6 5/6	Oversight and statutory decision-making on registration of Complementary medicines
12.	**Controlled Substances**	Air Commodore P . Zimondi (Chairperson) Dr C Duri Mr N Madzikwa Mr O Madhume Mr M.L Musiyambiri Mr M.H Sawyer Mr D. Matondo Dr A.M Dube Ms F . Ndlovu Mr P.F Takaza Mr D.T Savadye Dr. D. Kutywayo Ms R. Mudarikwa	3/4 3/4 2/4 4/4 4/4 0/4 4/4 2/4 4/4 4/4 3/4 3/4 3/4	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
13.	**Hearing**	Mr D.N Vuragu (Chairperson) Mrs N. Samuriwo Mr. D Moyo Mrs J. Ncube	5/5 2/5 4/5 5/5	Conducts hearings into matters referred to it from the Licensing and Advertising Committee and make appropriate decisions for and on behalf of the Authority.
14.	**Percentage Discount Company**	Mrs Y .M. Zhou (Chairperson) Mr D.N Vuragu Dr P . Muvavarirwa	5/5 5/5 4/5	Percentage Discount Company is a subsidiary of the Authority. The Members ensure establishment of systems to monitor and safeguard assets of the company.
15.	**ICT**	Mr P. Mwendera (Chairperson) Air Commodore P . Zimondi Ms C. Chanaiwa Mr M. Chikonye Mr G. Kabungaidze	5/5 4/5 3/5 4/5 4/5	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.

Governance and Risk Report

Management

The role of the Director-General is separate from that of the Chairman as prescribed in the MASCA (CAP 15:03) and also in line with corporate governance best practices. The Director-General is responsible for leading the implementation and execution of the Board approved strategy, operational planning and overseeing the day-to-day management of the Authority. The Director-General is assisted by a dedicated Management team whose duties include making operational decisions, developing appropriate and relevant policies and recommendations as well as keeping the Board informed about MCAZ operations.

The former Head EVR, Dr W. Wekwete, who was also one of the longest serving members of the Authority resigned in March 2022, but sadly passed away in early 2023. The Authority shall forever cherish the invaluable contributions made Dr Wekwete. May we continue to pray for his family to be consoled at the irreparable loss and may his dear soul rest in eternal peace.

Other Management team members who left the Authority in 2022 include the former Head Chemistry, Mr C. Shamhuyarira, former Head Finance, Mr E. Kulube, former Chief Regulatory Officer (LED), Ms A. Verenga and former Projects and Public Relations Manager, Dr T Makamure. The Authority would like to thank these members for their immense contributions during their tenure and wish them well in their careers.

The Authority also welcomed three new Management staff who include the ICT Manager (Mr Mukanga), Procurement & Admin Manager (Mr Vambe) and the Legal Manager (Mrs R Chimhenga) and would like to wish them a fruitful working career. Below is the 2022 MCAZ Management Team.

	Name	Position
1	Mr R. Rukwata	Acting Director-General/Head Licencing and Enforcement
2	Mr F. Masekele	Head EVR
3	Mrs P. Nyambayo	Head Pharmacovigilance & Clinical Trials
4	Mr. C Shamhuyarira	Head Chemistry
5	Mr E. Kulube	Head Finance
6	Dr T. Munhenga	Head Human Resources
7	Mr T. Gonho	Microbiology and Medical Devices Manager
8	Mrs A. Chikowore	Quality Manager
9	Mrs R. Chimhenga	Legal Manager
10	Ms R. Tugwete	Internal Auditor
11	Mrs R. Gwata	Finance Manager
12	Mr. T Mukanga	ICT Manager
13	Mr T. Vambe	Procurement & Administration Manager
14	Ms T. Muvirimi	Chief Regulatory Officer - EVR
15	Mrs C. Samatanga	Chief Regulatory Officer - LED
16	Mr K. Dzawo	Chief Analyst - Chemistry
17	Mr L. Chirinda	CRO PVCT

Governance and Risk Report

Internal Controls

The Board through the Audit Committee is responsible for ensuring that the Authority maintains an effective internal control environment. The Audit Committee delegates this responsibility to the Internal Audit Unit which is responsible for evaluating the effectiveness of the system of internal controls, risk management and governance processes to ensure that they are operating as prescribed. It is Management's responsibility to develop and maintain sound systems of risk management, internal control and governance and for the prevention and detection of irregularities and fraud, while Internal Audit is responsible for the assurance of the internal controls. To preserve independence of the Internal Audit function, the Internal Auditor reports administratively to the Director-General and functionally to the Audit Committee.

A total of nine audits were conducted in 2022, of which seven were scheduled audits as per the Internal Audit approved annual workplan whilst two were adhoc assignments. Follow up on implementation of the audit findings was also done since this is a key determinant of the Internal Audit performance. During 2022, a total of forty six (46) recommendations (i.e. 92%) were implemented out of fifty (50) and the Unit continues to follow up on the implementation of the remaining action items.

Risk Management

Risk management activities are embedded in the daily operations of the Authority through our three lines of defense model. This model has helped by increasing risk awareness within the organization, strengthening accountability for risk management and internal controls, and identifying which risks each Unit/function should monitor. The first line of assurance consists of the process owners/ HODs whose responsibility is to identify and monitor risks and execute strategies to mitigate the risks within their workstations and updating their Unit risk registers quarterly. The second line relates to the risk control function by our Quality Unit, which is responsible for monitoring Unit risk registers to ensure implementation and effectiveness of actions taken to address risks and opportunities identified. The third line of defence consists of the Internal Audit function which provides an independent assessment of the adequacy and effectiveness of overall risk management framework and risk governance structures and reports to the Authority through the Audit Committee of the Board.

Our global risk register is updated quarterly to include all the principal risks facing the Authority, including those that are externally influenced. The delayed approval of legislation remained a significant risk on the 2022 Global Risk Register, which has significantly affected the registration process and ability for MCAZ to participate competitively on International bids.

1.7 Deloitte Tip-Offs Anonymous

The Authority subscribes to Deloitte's Tip-Offs Anonymous Service for reporting fraud, corruption, dishonesty, harassment, conflict of interest and any other unethical behaviour in the workplace. A Fraud Management Committee is in place to receive Deloitte 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 Authority also has in place a Whistleblowing Policy that provides clear procedures for reporting through the Tip-Offs Anonymous platform. There were no substantial incident reports received from Deloittes during the period under review.

Auditor General's Report

All communication should be addressed to:
The Auditor-General
P. O. Box CY 143, Causeway, Harare
Telephone 263-242-793611/3/4
Telegrams: AUDITOR
E-mail: oagzimbabwe263@gmail.com
Website: www.auditorgeneral.gov.zw

OAG ZIMBABWE

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, 2022

Report on the Audit of the Consolidated Financial Statements

Opinion on the Consolidated Financial Statements

I have audited the accompanying consolidated financial statements of the Medicines Control Authority of Zimbabwe and its subsidiary ("the Group") as set out on pages 6 to 29, which comprise the consolidated statement of financial position as at December 31, 2022, 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.

In my opinion, the accompanying consolidated financial statements present fairly, in all material respects, the consolidated financial position of Medicines Control Authority of Zimbabwe as at December 31, 2022, 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 accompanying financial statements present fairly, in all material respects, the financial position of Medicines Control Authority of Zimbabwe as at December 31, 2022, and its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRSs).

Auditor General's Report

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS

for the year ended December 31, 2022

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, 2022. 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 audit matters to be communicated in my report.

Key Audit Matter	How my audit addressed the Key Audit Matter
Valuation of investment property. Refer to note 3.1.4 and 5 to the financial statements. The Group's investment property fair value increased from ZWL 696. 12 million to ZWL 1.06 billion. Valuation of the investment property is highly subjective due to the use of judgments and estimates in determining the fair values. The fair value was determined with reference to unobservable inputs which include rental per square metre, capitalisation rates and vacancy rates. As a result of the judgement applied by management in determining the fair values, the valuation of investment property was considered a key audit matter.	The audit procedures that I performed to address the risk of material misstatement relating to valuation of investment property included: • Reviewed the assumptions used for valuation of investment property carried at fair value. • Reviewed whether the basis of assumptions used comply in full with International Financial Reporting Standard (IFRS) 13- "Fair Value Measurement." Based on the evidence gathered ,I found that the Group's investment property was fairly valued and disclosures related to investment property were appropriate.
Valuation of property, plant and equipment. Refer to note 3.1.3 and 4 to the financial statements.	The audit procedures that I performed to address the risk of material misstatement relating to valuation of investment property included: • Reviewed documentary evidence supporting

Auditor General's Report

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS

for the year ended December 31, 2022

Key Audit Matter	How my audit addressed the Key Audit Matter
The Group held property, plant and equipment with a revalued carrying amount of ZWL3. 54 billion as at December 31, 2022 after adjusting for revaluation surplus of ZWL1. 56 billion. The valuation of the property, plant and equipment took into account unobservable inputs and therefore requires significant judgement in determining the fair values of property, plant and equipment as well as assessment of its useful life. As a result, valuation of property, plant and equipment was considered to be a key audit matter.	that valuation was performed by competent and experienced valuers. • Reviewed the assumptions used for revaluation of property, plant and equipment. • Reviewed the revaluation report to ascertain whether the fair values were determined in line with IFRS 13 - "Fair Value Measurement.". Based on the evidence obtained, I found that the valuation of property, plant and equipment was appropriate and disclosures adequate.

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 2022 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 ("the Other Information").

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

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS

for the year ended December 31, 2022

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.

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 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, 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 soley responsible for my audit opinion.

Auditor General's Report

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS

for the year ended December 31, 2022

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 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*], Companies and Other Business Entities Act *[Chapter 24:31] and* other relevant Statutory Instruments.

18 July , 2023.

R. KUJINGA,
ACTING-AUDITOR-GENERAL.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

as at December 31, 2022

	Note	MCAZ GROUP				AUTHORITY			
		Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
ASSETS		2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL
Non-current assets		**4 608 606 256**	**2 826 518 782**	**4 608 340 790**	**805 364 584**	**4 237 961 852**	**2 692 949 998**	**4 054 595 711**	**746 877 087**
Property, plant and equipment	4	3 548 606 256	2 130 401 331	3 548 340 790	602 863 484	2 994 377 115	1 928 290 751	2 994 377 116	544 157 392
Investment property	5	1 060 000 000	696 117 451	1 060 000 000	202 501 100	1 060 000 000	696 117 451	1 060 000 000	202 501 100
Investment in subsidiary	6	-	-	-	-	183 584 737	68 541 796	218 595	218 595
Current assets		**3 276 407 456**	**1 885 170 003**	**3 169 960 820**	**548 369 797**	**3 235 629 775**	**1 871 409 196**	**3 129 183 139**	**544 366 768**
Inventory	7	121 680 557	7 121 463	15 233 921	2 044 037	121 680 557	7 121 463	15 233 921	2 044 037
Trade and other receivables	8	346 389 201	72 867 336	346 389 201	21 197 164	348 151 961	72 607 670	348 151 961	21 121 627
Cash and cash equivalents	9	2 808 337 698	1 805 181 204	2 808 337 698	525 128 596	2 765 797 257	1 791 680 063	2 765 797 257	521 201 104
Total assets		**7 885 013 712**	**4 711 688 785**	**7 778 301 610**	**1 353 734 381**	**7 473 591 627**	**4 564 359 194**	**7 183 778 850**	**1 291 243 855**
RESERVES AND LIABILITIES									
Reserves		**6 839 168 757**	**3 837 060 553**	**7 125 601 759**	**1 204 659 653**	**6 574 985 870**	**3 738 427 241**	**6 683 913 374**	**1 156 334 912**
Capital reserve		1 305 905 328	1 305 905 328	5 444 017	5 444 017	1 305 905 328	1 305 905 328	5 444 017	5 444 017
Accumulated fund		2 482 658 207	1 042 070 439	3 698 709 899	526 564 516	2 727 283 901	1 085 924 537	3 784 780 847	626 407 660
Revaluation reserve		2 500 949 013	1 054 471 408	3 138 198 665	550 681 035	2 541 796 641	1 346 597 376	2 893 688 510	524 483 235
Non-controlling interest		549 656 209	434 613 378	283 249 178	121 970 085	-	-	-	-
Non-current liabilities		**552 877 749**	**460 399 179**	**159 732 645**	**28 575 179**	**410 475 428**	**411 721 576**	**11 735 147**	**14 414 827**
Deferred income	10	410 475 428	411 721 576	11 735 147	14 414 827	410 475 428	411 721 576	11 735 147	14 414 827
Deferred tax liability	11	142 402 321	48 677 603	147 997 498	14 160 352	-	-	-	-
Current liabilities		**492 967 206**	**414 229 053**	**492 967 206**	**120 499 549**	**488 130 329**	**414 210 377**	**488 130 329**	**120 494 116**
Trade and other payables	12	480 906 861	396 602 626	480 906 861	115 372 008	476 069 984	396 583 950	476 069 984	115 366 575
Provisions	13	10 154 493	13 248 508	10 154 493	3 854 001	10 154 493	13 248 508	10 154 493	3 854 001
Deferred income	10	1 905 852	4 377 919	1 905 852	1 273 540	1 905 852	4 377 919	1 905 852	1 273 540
Total reserves and liabilities		**7 885 013 712**	**4 711 688 785**	**7 778 301 610**	**1 353 734 381**	**7 473 591 627**	**4 564 359 194**	**7 183 778 850**	**1 291 243 855**

10 July, 2023.

10 July, 2023.

12/07/2023, 2023.

N. Samusodza, Bachelor of Commerce Finance,
(ACTING-FINANCE MANAGER).

R. Rukwata,
(DIRECTOR- GENERAL).

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, 2021

	Note	MCAZ GROUP				AUTHORITY			
		Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
		2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL
INCOME		**5 847 422 892**	**2 635 199 798**	**5 215 090 898**	**691 448 951**	**5 797 568 149**	**2 620 411 628**	**5 171 231 453**	**687 892 548**
Medicines control income	14	2 409 911 663	1 618 220 346	1 583 248 756	368 374 698	2 409 911 663	1 618 220 346	1 583 248 756	368 374 698
Laboratory services	15	535 681 524	319 125 951	407 295 294	77 552 513	535 681 524	319 125 952	407 295 294	77 552 513
Other income	16	2 901 829 705	697 853 501	3 224 546 848	245 521 740	2 851 974 962	683 065 330	3 180 687 403	241 965 337
LESS EXPENDITURE		**2 913 421 915**	**1 754 101 839**	**2 036 814 435**	**382 820 344**	**2 892 101 085**	**1 749 283 819**	**2 017 556 269**	**381 704 974**
Administration expenses	17	1 196 441 276	698 669 594	806 188 370	132 605 909	1 175 120 446	693 851 574	786 930 204	131 490 539
Other expenses	18	1 716 980 639	1 055 432 245	1 230 626 065	250 214 435	1 716 980 639	1 055 432 245	1 230 626 065	250 214 435
Operating surplus for the year		**2 934 000 977**	**881 097 959**	**3 178 276 463**	**308 628 607**	**2 905 467 064**	**871 127 809**	**3 153 675 184**	**306 187 574**
Monetary loss		(1 489 702 742)	(643 391 432)	-	-	(1 267 212 224)	(626 614 324)	-	-
Surplus before taxation		**1 444 298 235**	**237 706 527**	**3 178 276 463**	**308 628 607**	**1 638 254 840**	**244 513 485**	**3 153 675 184**	**306 187 574**
Taxation		(1 258 576)	(1 420 754)	(1 258 576)	(413 298)	-	-	-	-
Surplus after taxation		**1 443 039 659**	**236 285 773**	**3 177 017 887**	**308 215 309**	**1 638 254 840**	**244 513 485**	**3 153 675 184**	**306 187 574**
Other comprehensive income									
Revaluation gain		1 559 068 545	513 063 736	2 743 924 219	480 968 076	1 198 303 789	501 521 600	2 373 903 278	463 629 199
Total other comprehensive income		**1 559 068 545**	**513 063 736**	**2 743 924 219**	**480 968 076**	**1 198 303 789**	501 521 600	**2 373 903 278**	**463 629 199**
Total comprehensive income		**3 002 108 204**	**749 349 509**	**5 920 942 106**	**789 183 385**	**2 836 558 629**	**746 035 085**	**5 527 578 462**	**769 816 773**
Surplus attributable to:									
Equity holders of the parent		1 437 483 244	238 714 808	3 167 447 380	307 383 938	1 638 254 840	244 513 485	3 153 675 184	306 187 574
Non-controlling interest		5 556 415	2 429 035	9 570 507	831 371	-	-	-	-
Surplus for the year		**1 443 039 659**	**236 285 773**	**3 177 017 887**	**308 215 309**	**1 638 254 840**	**244 513 485**	**3 153 675 184**	**306 187 574**
Other comprehensive income attributable to:									
Equity holders of the parent		1 449 582 129	508 331 459	2 592 215 633	473 859 136	1 198 303 789	501 521 600	2 373 903 278	463 629 199
Non-controlling interest		109 486 416	4 732 277	151 708 586	7 108 940	-	-	-	-
Total comprehensive income		**1 559 068 545**	**513 063 736**	**2 743 924 219**	**480 968 076**	**1 198 303 789**	**501 521 600**	**2 373 903 278**	**463 629 199**

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

for the year ended December 31, 2021

	Note	MCAZ GROUP				AUTHORITY			
		Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
		2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL
INCOME		**5 847 422 892**	**2 635 199 798**	**5 215 090 898**	**691 448 951**	**5 797 568 149**	**2 620 411 628**	**5 171 231 453**	**687 892 548**
Medicines control income	14	2 409 911 663	1 618 220 346	1 583 248 756	368 374 698	2 409 911 663	1 618 220 346	1 583 248 756	368 374 698
Laboratory services	15	535 681 524	319 125 951	407 295 294	77 552 513	535 681 524	319 125 952	407 295 294	77 552 513
Other income	16	2 901 829 705	697 853 501	3 224 546 848	245 521 740	2 851 974 962	683 065 330	3 180 687 403	241 965 337
LESS EXPENDITURE		**2 913 421 915**	**1 754 101 839**	**2 036 814 435**	**382 820 344**	**2 892 101 085**	**1 749 283 819**	**2 017 556 269**	**381 704 974**
Administration expenses	17	1 196 441 276	698 669 594	806 188 370	132 605 909	1 175 120 446	693 851 574	786 930 204	131 490 539
Other expenses	18	1 716 980 639	1 055 432 245	1 230 626 065	250 214 435	1 716 980 639	1 055 432 245	1 230 626 065	250 214 435
Operating surplus for the year		**2 934 000 977**	**881 097 959**	**3 178 276 463**	**308 628 607**	**2 905 467 064**	**871 127 809**	**3 153 675 184**	**306 187 574**
Monetary loss		(1 489 702 742)	(643 391 432)	-	-	(1 267 212 224)	(626 614 324)	-	-
Surplus before taxation		**1 444 298 235**	**237 706 527**	**3 178 276 463**	**308 628 607**	**1 638 254 840**	**244 513 485**	**3 153 675 184**	**306 187 574**
Taxation		(1 258 576)	(1 420 754)	(1 258 576)	(413 298)	-	-	-	-
Surplus after taxation		**1 443 039 659**	**236 285 773**	**3 177 017 887**	**308 215 309**	**1 638 254 840**	**244 513 485**	**3 153 675 184**	**306 187 574**
Other comprehensive income									
Revaluation gain		1 559 068 545	513 063 736	2 743 924 219	480 968 076	1 198 303 789	501 521 600	2 373 903 278	463 629 199
Total other comprehensive income		**1 559 068 545**	**513 063 736**	**2 743 924 219**	**480 968 076**	**1 198 303 789**	501 521 600	**5 527 578 462**	**769 816 773**
Total comprehensive income		**3 002 108 204**	**749 349 509**	**5 920 942 106**	**789 183 385**	**2 836 558 629**	**746 035 085**	**5 527 578 462**	**769 816 773**
Surplus attributable to:									
Equity holders of the parent		1 437 483 244	238 714 808	3 167 447 380	307 383 938	1 638 254 840	244 513 485	3 153 675 184	306 187 574
Non-controlling interest		5 556 415	2 429 035	9 570 507	831 371	-	-	-	-
Surplus for the year		**1 443 039 659**	**236 285 773**	**3 177 017 887**	**308 215 309**	**1 638 254 840**	**244 513 485**	**3 153 675 184**	**306 187 574**
Other comprehensive income attributable to:									
Equity holders of the parent		1 449 582 129	508 331 459	2 592 215 633	473 859 136	1 198 303 789	501 521 600	2 373 903 278	463 629 199
Non-controlling interest		109 486 416	4 732 277	151 708 586	7 108 940	-	-	-	-
Total comprehensive income		**1 559 068 545**	**513 063 736**	**2 743 924 219**	**480 968 076**	**1 198 303 789**	**501 521 600**	**2 373 903 278**	**463 629 199**

Audited Financial Statement

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

STATEMENT OF CHANGES IN RESERVES

for the year ended December 31, 2022

Group Inflation adjusted	Accumulated fund ZWL	Capital reserve ZWL	Revaluation reserve ZWL	Total ZWL	Non-controlling interest ZWL	Total reserves ZWL
Balance as at January 1, 2021	**803 355 631**	**1 305 905 328**	**556 812 056**	**2 666 073 015**	**432 310 136**	**3 098 383 151**
Surplus for the year	238 714 808	-	-	**238 714 808**	(2 429 035)	**236 285 773**
Revaluation surplus	-	-	508 331 459	**508 331 459**	4 732 277	**513 063 736**
Elimination of unrealised gain on disposal	-	-	(10 672 107)	**(10 672 107)**	-	**(10 672 107)**
Balance as at December 31, 2021	**1 042 070 439**	**1 305 905 328**	**1 054 471 408**	**3 402 447 175**	**434 613 378**	**3 837 060 553**
Balance as at January 1, 2022	**1 042 070 439**	**1 305 905 328**	**1 054 471 408**	**3 402 447 175**	**434 613 378**	**3 837 060 553**
Surplus for the year	1 437 483 244	-	-	1 437 483 244	5 556 415	**1 443 039 659**
Revaluation surplus	-	-	1 449 582 129	1 449 582 129	109 486 416	**1 559 068 545**
Elimination of realised gain on disposed asset	3 104 524	-	(3 104 524)	-	-	-
Balance as at December 31, 2022	**2 482 658 207**	**1 305 905 328**	**2 500 949 013**	**6 289 512 548**	**549 656 209**	**6 839 168 757**

Historical cost	Accumulated fund ZWL	Capital reserve ZWL	Revaluation reserve ZWL	Total ZWL	Non-controlling interest ZWL	Total reserves ZWL
Balance as at January 1, 2021	**219 180 578**	**5 444 017**	**77 015 025**	**301 639 620**	**114 029 774**	**415 669 394**
Surplus for the year	307 383 938	-	-	**307 383 938**	831 371	**308 215 309**
Revaluation surplus	-	-	473 859 136	**473 859 136**	7 108 940	**480 968 076**
Elimination of realised gain on disposal	-	-	(193 126)	**(193 126)**	-	**(193 126)**
Balance as at December 31, 2021	**526 564 516**	**5 444 017**	**550 681 035**	**1 082 689 568**	**121 970 085**	**1 204 659 653**
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**
Revaluation surplus	-	-	2 592 215 633	**2 592 215 633**	151 708 586	**2 743 924 219**
Elimination of realised gain on disposed asset	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**

Audited Financial Statement

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

STATEMENT OF CHANGES IN RESERVES

for the year ended December 31, 2022

Authority Inflation adjusted	Accumulated fund ZWL	Capital reserve ZWL	Revaluation reserve ZWL	Total ZWL
Balance as at January 1, 2021	841 411 052	1 305 905 328	855 747 883	**3 003 064 263**
Surplus for the year	244 513 485	-	-	**244 513 485**
Revaluation surplus	-	-	501 521 600	**501 521 600**
Elimination on realised gain on disposal	-	-	(10 672 107)	**(10 672 107)**
Balance as at December 31, 2021	**1 085 924 537**	**1 305 905 328**	**1 346 597 376**	**3 738 427 241**
Balance as at January 1, 2022	**1 085 924 537**	**1 305 905 328**	**1 346 597 376**	**3 738 427 241**
Surplus for the year	1 638 254 840	-	-	**1 638 254 840**
Revaluation surplus	-	-	1 198 303 789	**1 198 303 789**
Elimination of realised gain on disposal	3 104 524	-	(3 104 524)	-
Balance as at December 31, 2022	**2 727 283 901**	**1 305 905 328**	**2 541 796 641**	**6 574 985 870**

Authority Historical cost	Accumulated fund ZWL	Capital reserve ZWL	Revaluation reserve ZWL	Total ZWL
Balance as at January 1, 2021	320 220 086	5 444 017	61 047 162	**386 711 265**
Surplus for the year	306 187 574	-	-	**306 187 574**
Revaluation surplus	-	-	463 629 199	**463 629 199**
Elimination of realised gain on disposal	-	-	(193 126)	**(193 126)**
Balance as at December 31, 2021	**626 407 660**	**5 444 017**	**524 483 235**	**1 156 334 912**
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**
Revaluation surplus	-	-	2 373 903 278	**2 373 903 278**
Elimination of realised gain on disposal	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**

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

CONSOLIDATED STATEMENT OF CASH FLOWS

for the year ended December 31, 2022

	Note	MCAZ GROUP				AUTHORITY			
		Inflation adjusted		Historical cost		Inflation adjusted			
		2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL
Net cash flow from operating activities		**(12 493 859)**	**(94 212 874)**	**1 319 555 783**	**151 824 140**	**(42 791 735)**	**(100 330 067)**	**1 279 684 256**	**149 045 828**
Surplus for the year		1 444 298 235	237 706 527	3 178 276 463	308 628 607	1 638 254 840	244 513 485	3 153 675 184	306 187 574
Adjusted for non cash items:		**(1 153 015 370)**	**(363 877 807)**	**(1 885 873 612)**	**(195 304 515)**	**(1 370 429 224)**	**(376 740 212)**	**(1 894 474 119)**	**(195 641 272)**
Depreciation charge for the year	4	206 328 801	173 605 026	36 817 109	7 223 148	197 682 606	172 115 449	28 216 602	6 879 917
Increase/(decrease) in provision for leave pay		(3 094 015)	9 370 821	6 300 492	3 152 231	(3 094 015)	9 370 821	6 300 492	3 152 231
Fair value adjustment on investment property		(363 882 549)	(239 092 536)	(857 498 900)	(119 790 340)	(363 882 549)	(239 092 536)	(857 498 900)	(119 790 340)
Deferred income amortisation		(3 718 215)	(6 827 981)	(2 047 368)	(1 380 524)	(3 718 215)	(6 827 981)	(2 047 368)	(1 380 524)
Loss on disposal of property, plant and equipment		10 232 020	673 216	3 564 649	173 581	10 232 020	673 216	3 564 649	173 581
Adjustment of duplicated assets	4	-	40 213	-	73 962	-	40 213	-	73 962
Realised gain on disposed asset		-	(10 672 107)	-	(193 126)	-	(10 672 107)	-	(193 126)
Exchange gains-unrealised		(1087 282 314)	(290 669 592)	(1068 474 724)	(84 556 007)	(1087 282 314)	(290 669 592)	(1068 474 724)	(84 556 007)
Interest earned		(5 323 816)	(30 715)	(4 534 870)	(7 440)	(5 323 816)	(4 699)	(4 534 870)	(966)
Net monetary gain/(loss)		93 724 718	(274 152)	-	-	(115 042 941)	(11 672 996)	-	-
Working capital changes:		**(303 776 724)**	**31 958 406**	**27 152 932**	**38 500 048**	**(310 617 351)**	**31 896 660**	**20 483 191**	**38 499 526**
Increase in inventory	7	(114 559 094)	(103 235)	(13 189 884)	(1 208 666)	(114 559 094)	(103 235)	(13 189 884)	(1 208 666)
(Increase)/decrease in trade and other receivables	8	(273 521 865)	13 443 897	(325 192 037)	(5 561 024)	(275 544 291)	13 373 684	(327 030 334)	(5 561 024)
Increase in trade and other payables	12	84 304 235	18 617 744	365 534 853	45 269 738	79 486 034	18 626 211	360 703 409	45 269 216
Income tax paid		(1 258 576)	(1 718 517)	(1 258 576)	(499 918)	-	-	-	-
Net cash flow from investing activities:		**(70 373 385)**	**(48 637 496)**	**(103 562 827)**	**(11 006 181)**	**(70 373 385)**	**(48 663 512)**	**(103 562 827)**	**(11 012 655)**
Purchase of property, plant and equipment	4	(78 053 761)	(50 949 659)	(108 274 213)	(11 037 871)	(78 053 761)	(50 949 659)	(108 274 213)	(11 037 871)
Proceeds from disposal of property, plant and equipment		2 356 560	2 281 448	176 516	24 250	2 356 560	2 281 448	176 516	24 250
Interest received		5 323 816	30 715	4 534 870	7 440	5 323 816	4 699	4 534 870	966
Net (decrease)/increase in cash and cash equivalents		**(84 125 820)**	**(144 568 887)**	**1 214 734 380**	**140 318 041**	**(113 165 120)**	**(148 993 579)**	**1 176 121 429**	**138 033 173**
Exchange gain on cash and cash equivalents		**1 087 282 314**	**290 669 592**	**1 068 474 722**	**84 556 007**	**1 087 282 314**	**290 669 592**	**1 068 474 724**	**84 556 007**
Cash and cash equivalents at beginning of the year		**1 805 181 204**	**1 659 080 499**	**525 128 596**	**300 254 548**	**1 791 680 063**	**1 650 004 050**	**521 201 104**	**298 611 924**
Cash and cash equivalents at year end	9	**2 808 337 698**	**1 805 181 204**	**2 808 337 698**	**525 128 596**	**2 765 797 257**	**1 791 680 063**	**2 765 797 257**	**521 201 104**

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2022

1. NATURE OF BUSINESS

The Medicines Control Authority of Zimbabwe was established in terms of 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").

2.2 Basis of measurement

The Group's financial statements are prepared under the historical cost convention, except for property, plant and equipment shown at revalued amounts and Investment property which is measured at fair value.

2.3 Functional and presentation currency

These financial statements are presented in Zimbabwe Dollars (ZWL) currency as prescribed under Statutory Instrument 33 of 2019 dated 22nd February 2019 and in Statutory Instrument 142 of 2019 dated 24th June 2019. The Authority adopted the Zimbabwe Dollar (ZWL) as the functional and presentation currency in order to comply with IAS 21, the effects of changes in foreign currency exchange rates. Most of the Authority's transactions are in this currency and the same is used for the reporting. All foreign currency transactions were translated to (ZWL) using the official rate at the date of the transaction.

2.4 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. The Public Accountants and Auditors Board (PAAB) pronounced that the economy is trading under conditions of hyperinflation in line with IAS 29. Management have applied the guidelines provided by PAAB. Management made various assumptions to produce the inflation adjusted financial information. The conversion factors have been computed from the consumer price index (CPI) data as provided by Zimbabwe Statistical Agency (ZIMSTATS) on their website and also as circulated by PAAB.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2022

Month	Index	Conversion Factor
30-Jun-21	2 986.44	1.33
31-Jul-21	3 062.93	1.30
31-Aug-21	3 191.19	1.25
30-Sep-21	3 342.02	1.19
31-Oct-21	3 555.90	1.12
30-Nov-21	3 760.86	1.06
31-Dec-21	3 977.46	1.00
30-Jan-22	4 189.97	3.26
28-Feb-22	4 483.06	3.05
30-Mar-22	4 766.10	2.87
30-Apr-22	5 507.11	2.48
31-May-22	6 662.17	2.05
30-Jun-22	8 707.35	1.57
31-Jul-22	10 932.83	1.25
31-Aug-22	12 286.26	1.11
30-Sep-22	12 713.12	1.08
31-Oct-22	13 113.95	1.04
30-Nov-22	13 349.42	1.02
31-Dec-22	13 672.91	1.00

2.5 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

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2022

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:

2.5.1 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.

2.5.2 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.

2.5.3 Fair value measurement

The fairvalue 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 proffessional standards are mantained.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2022

2.5.4 Expected credit losses

The expected credit loss model applies to 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 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 on receivables that are more than 3 months. Expected credit losses is the exposure at default times the probability of default.

2.6 Amended Standards – Effective January 1, 2022

i. Amendment to International Accounting Standard (IAS) 1, presentation of financial statements on classification of liabilities as current or non-current

The amendment clarifies that liabilities are classified as either current or non-current depending on the rights that exist at the end of the reporting period. Classification in unaffected by expectations of the entity or events after the reporting date (for example the receipt of a waiver or a reach of covenant).

ii. Amendments to International Accounting Standard (IAS) 16 property, plant and equipment on proceeds before intended use

The amendment to IAS 16, prohibits an entity from deducting from the cost of an item of property, plant and equipment any proceeds received from selling items produced while the entity is preparing the asset for its intended use (for example, the proceeds from selling samples produced when testing a machine to see if it is functioning properly) The proceeds from selling such items, together with the costs of producing them are recognised in profit or loss.

iii. Amendment to International Accounting Standard (IAS) 37 provisions, contingent liabilities and contingent assets 'on onerous contracts- cost - cost of fulfilling a contract.

The amendment clarifies which costs an entity includes in assessing whether a contract will be loss-making. This assessment is made by considering unavoidable costs, which are the lower of the net cost of exiting the contract and the costs to fulfil the contract. The amendment clarifies the meaning of 'costs to fulfil contract' Under the amendment, costs to fulfil a contract include incremental costs and the allocation of other costs that relate directly to fulfilling the contract.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2022

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iv. Amendment to International Financial Reporting Standard (IFRS) 1- "First-time Adoption of International Financial Reporting Standards"

The amendment permits a subsidiary to measure cumulative translation differences using the amounts reported by its parent, based on the parent's date of transition to IFRSs.

v. International Financial Reporting Standard (IFRS) 16, "Leases" COVID -19 related rent concessions amendment

The IASB has provided lessees (but not lessors) with relief in the form of an optional exemption from assessing whether a rent concession related to COVID-19 is a lease modification, provided that the concession meets certain conditions. Lessees can elect to account for qualifying rent concessions in the same way as they would if they were not lease modifications. In many cases, this will result in accounting for the concession as a variable lease payment.

2.7 Basis of Consolidation

2.7.1 Group

The consolidated financial statements comprise the financial statements of Medicines Control Authority of Zimbabwe and its subsidiary, Percentage Discount as at December 31, 2022.

2.7.2 Subsidiary

The Authority's policy on accounting for subsidiary is to fully consolidate 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 subsidiaries are 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.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2022

2.7.2.1 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.

2.7.2.2 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, 2022

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, 2021.

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 stated at cost less accumulated 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, 2022

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. If a revalued asset is subsequently disposed out of the Group, any remaining revaluation surplus is credited to the accumulated fund.

3.1.4 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 under fair value model. Any gains or losses on disposal of an investment property is recognised in profit or loss. When the use of a property changes such that it is reclassified as property, plant and equipment, its fair value at the date of reclassification becomes its cost for subsequent accounting.

3.1.5 Leases

It introduced significant changes to lessee accounting by removing the distinction between operating and finance leases and requiring the recognition of a right-of-use asset and a lease liability at the lease commencement for all leases, except for short-term leases and leases of low value assets. In contrast to lessee accounting, the requirements for lessor accounting have remained largely unchanged.

The Authority recognizes income from leases over the lease term of an operating lease, based on a pattern reflecting a constant periodic rate of return on the net investment. The Authority collects rentals from the Investment property. The leases are net rental income as all of the costs associated with the assets such as maintenance, insurance and property taxes are deducted from the rental income collected.

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

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2022

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

3.3 Taxation

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. 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. The Group's liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the statement of financial position date.

Deferred tax is recognised on difference between carrying amounts of assets and the liabilities in the financial statements and the corresponding tax base used in the computation of taxable profit, and is accounted for using the Statement of Financial Position liability method. Deferred tax liabilities are generally recognized for all taxable temporary differences and deferred tax assets are recognized to the extent that it is probable that taxable profits will be available against which deductible temporary differences arise from the initial recognition (other than in a business combination) of other assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit.

The carrying amount of deferred tax assets is reviewed at each statement of financial position date and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered.

Deferred tax is calculated at the tax rates that are expected to apply in the period when the liability is settled or the asset realized. Deferred tax is charged or credited to profit or loss, except when it relates to items charged directly to equity, in which case the deferred tax is also dealt in equity. Deferred tax assets and liabilities are offset when there is legally enforceable right to set off current tax assets against current tax liabilities and when they relate to income taxes levied by the same tax authority and the Group intends to settle its current tax assets and liabilities on a net basis.

Current and deferred income tax

Current income tax liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. Deferred income tax is provided using the full balance sheet liability method on temporary differences at year end between the tax bases of assets and liabilities at year end between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences. Deferred tax assets are recognised for all deductible temporary differences and carrying forward of unused tax losses, 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 losses can be utilized.

The Authority is exempted from paying corporate tax.

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)
- 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.
Financial assets at amortised cost	These assets are subsequently measured at amortised cost using the effective interest method. The amortised cost is reduced by impairment losses. Interest income, foreign exchange gains and losses, and impairment are recognised in profit or loss. Any gain or loss on derecognition is recognised in profit or loss.
Debt investments at FVOCI	These assets are subsequently measured at fair value. Interest income calculated using the effective interest method, foreign exchange gains and losses, and impairment are recognised in profit or loss. Other net gains and losses are recognised in other comprehensive income. On derecognition, gains and losses accumulated in other comprehensive income are reclassified to profit or loss.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2022

Equity investments at FVOCI	These assets are subsequently measured at fair value. Dividends are recognised as income in profit or loss unless the dividend clearly represents a recovery of part of the cost of the investment. Other net gains and losses are recognised in other comprehensive income and are never reclassified to profit or loss.

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.

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

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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not consider otherwise, indications that a debtor will enter bankruptcy, changes in the payment status, and disappearance of an active market for a security.

3.4.2 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.

3.6 Revenue recognition

The Group follows IFRS 15's five-step model when recognizing revenue through:

Step 1 Identify the contract(s) with a customer.

Step 2 Identify the performance obligations in the contract.

Step 3 Determine the transaction price.

Step 4 Allocate the transaction price to the performance obligations in the contract.

Step 5 Recognize revenue when (or as) the entity satisfies a performance obligation.

3.6.1 Below is a table showing the revenue for the Group and how the performance obligation is satisfied:

REVENUE LINE	PERFORMANCE OBLIGATION
Permits/Licenses	When permits or licenses have been issued.
Registration	When the client has been issued with a registration certificate.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2022

Renewals	When the client has been issued with a renewal certificate.
Retention	When a customer has been issued with the retention statement.
GMP Inspections	When GMP inspections has been performed.

3.6.2 Revenue from Permits, Licenses, Registration fees, Retention fees and Good Manufacturing Practice (GMP) Inspection fees is recognized at a point in time.

MCAZ GROUP

4 Property, plant and equipment

Inflation adjusted

	Freehold land ZWL	Buildings ZWL	Plant and machinery ZWL	Motor vehicles ZWL	Computer and equipment ZWL	Office equipment ZWL	Furniture and fittings ZWL	Work in progress ZWL	Total 2022 ZWL	Total 2021 ZWL
Opening carrying amount	**629 847 448**	**1 065 665 469**	**252 477 085**	**25 372 446**	**37 244 167**	**23 458 157**	**36 110 358**	**60 226 201**	**2 130 401 331**	**1 673 530 165**
Gross carrying amount	629 847 448	1 197 931 959	378 006 717	107 888 819	168 262 337	52 645 839	53 430 158	60 226 201	2 648 239 478	2 036 325 497
Accumulated depreciation		(132 266 490)	(125 529 632)	(82 516 373)	(131 018 170)	(29 187 682)	(17 319 800)	-	(517 838 147)	(362 795 332)
Additions at cost	-	-	33 783 991	58 397 782	16 459 433	4 461 210	24 101 182	(59 149 837)	78 053 761	50 949 659
Donated assets at cost	-	-	-	-	-	-	-	-	-	69 457 675
Duplicated assets	-	-	-	-	-	-	-	-	-	(40 213)
Gross carrying amount	-	-	-	-	-	-	-	-	-	(4 238 888)
Accumulated depreciation	-	-	-	-	-	-	-	-	-	4 198 675
Revaluation	**353 312 553**	**807 839 915**	**109 744 386**	**127 395 445**	**126 342 517**	**16 586 872**	**17 846 857**	**-**	**1 559 068 545**	**513 063 736**
Gross carrying amount	353 312 553	807 839 915	109 744 386	127 395 445	126 342 517	16 586 872	17 846 857	-	1 559 068 545	513 063 736
Accumulated depreciation	-	-	-	-	-	-	-	-	-	-
Disposals carrying amount	-	-	-	**(12 597 683)**	**9 103**	-	-	-	**(12 588 580)**	**(2 954 665)**
Disposals at cost	-	-	-	(17 730 405)	(238 915)	-		-	(17 969 320)	(17 318 201)
Accumulated depreciation	-	-	-	5 132 722	248 018	-	-	-	5 380 740	14 363 536
Depreciation charge for the year	-	(33 903 955)	(53 684 819)	(37 342 794)	(48 032 327)	(17 399 260)	(15 965 646)	-	(206 328 801)	(173 605 026)
Closing carrying amount	**983 160 001**	**1 839 601 429**	**342 320 643**	**161 225 196**	**132 022 893**	**27 106 979**	**62 092 751**	**1 076 364**	**3 548 606 256**	**2 130 401 331**
Gross carrying amount	983 160 001	2 005 771 874	521 535 094	275 951 641	310 825 372	73 693 921	95 378 197	1 076 364	4 267 392 464	2 648 239 478
Accumulated depreciation	-	(166 170 445)	(179 214 451)	(114 726 445)	(178 802 479)	(46 586 942)	(33 285 446)	-	(718 786 208)	(517 838 147)

Historical cost

	Freehold land ZWL	Buildings ZWL	Plant and machinery ZWL	Motor vehicles ZWL	Computer and equipment ZWL	Office equipment ZWL	Furniture and fittings ZWL	Work in progress ZWL	Total 2022 ZWL	Total 2021 ZWL
Opening carrying amount	**183 223 101**	**310 002 901**	**73 354 467**	**7 380 937**	**10 848 344**	**6 823 997**	**10 511 045**	**718 692**	**602 863 484**	**96 789 132**
Gross carrying amount	183 223 101	392 033 834	97 208 454	55 842 904	19 780 479	138 500 677	34 039 865	718 692	921 348 006	142 685 198
Accumulated depreciation	-	(82 030 933)	(23 853 987)	(48 461 967)	(8 932 135)	(131 676 680)	(23 528 820)	-	(318 484 522)	(45 896 066)
Additions at cost	-	-	29 822 730	44 414 765	15 094 272	4 060 947	14 523 827	357 672	108 274 213	11 037 871
Donated assets at cost	-	-	-	-	-	-	-	-	-	14 549 509
Duplicated assets	-	-	-	-	-	-	-	-	-	(73 962)
Gross carrying amount	-	-	-	-	-	-	-	-	-	(298 890)
Accumulated depreciation	-	-	-	-	-	-	-	-	-	224 928
Revaluation	**799 936 899**	**1 545 558 930**	**247 225 969**	**117 388 676**	**109 559 881**	**18 506 761**	**39 584 251**	**-**	**2 877 761 367**	**487 981 913**
Gross carrying amount	799 936 899	1 917 435 197	1 099 777 369	1 093 245 178	61 993 477 805	3 094 369 272	183 876 594		70 182 118 314	755 707 894
Accumulated depreciation	-	(371 876 267)	(852 551 400)	(975 856 502)	(61883 917 924)	(3075 862 511)	(144 292 343)	-	(67304 356 947)	(267 725 981)
Disposals carrying amount	-	-	-	**(3 726 437)**	**(14 728)**	-	-	-	**(3 741 165)**	**(197 831)**
Disposals at cost	-	-	-	(8 108 670)	(17 242)	-	-	-	(8 125 912)	(2 333 576)
Accumulated depreciation	-	-	-	4 382 233	2 514	-	-	-	4 384 747	2 135 745
Depreciation charge for the year	-	(15 960 940)	(8 347 475)	(4 232 721)	(3 464 875)	(2 284 726)	(2 526 372)	-	(36 817 109)	(7 223 148)
Closing carrying amount	**983 160 000**	**1 839 600 891**	**342 055 691**	**161 225 220**	**132 022 894**	**27 106 979**	**62 092 751**	**1 076 364**	**3 548 340 790**	**602 863 484**
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)	(1024 168 957)	(61896 312 420)	(3209 823 917)	(170 347 535)	-	(67655 273 831)	(318 484 522)

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4.1 Property, plant and equipment

Inflation adjusted

	Freehold land ZWL	Buildings ZWL	Plant and machinery ZWL	Motor vehicles ZWL	Computer and equipment ZWL	Office equipment ZWL	Furniture and fittings ZWL	Work in progress ZWL	Total 2022 ZWL	Total 2021 ZWL
Opening carrying amount	481 558 031	1 012 158 213	252 163 154	25 372 470	37 244 167	23 458 157	36 110 358	60 226 201	1 928 290 751	1 481 472 143
Gross carrying amount	481 558 031	1 134 787 130	377 544 769	107 888 842	168 262 337	52 645 839	53 430 158	60 226 201	2 436 343 307	1 835 971 463
Accumulated depreciation	-	(122 628 917)	(125 381 615)	(82 516 372)	(131 018 170)	(29 187 682)	(17 319 800)	-	(508 052 556)	(354 499 320)
Additions at cost	-	-	33 783 991	58 397 782	16 459 433	4 461 210	24 101 182	(59 149 837)	78 053 761	50 949 659
Donated assets at cost	-	-		-		-	-	-	-	69 457 675
Duplicated assets	-	-	-	-	-	-	-	-	-	(40 213)
Gross carrying amount	-	-	-	-		-		-	-	(4 238 889)
Accumulated depreciation	-	-	-	-	-	-	-	-	-	4 198 676
Revaluation	282 641 970	517 745 742	109 744 386	127 395 445	126 342 517	16 586 872	17 846 857	-	1 198 303 789	501 521 600
Gross carrying amount	282 641 970	517 745 742	109 744 386	127 395 445	126 342 517	16 586 872	17 846 857	-	1 198 303 789	501 521 600
Accumulated depreciation	-		-	-	-	-	-	-	-	
Disposals carrying amount	-	-	-	(12 597 683)	9 103	-	-	-	12 588 580	(2 954 664)
Disposals at cost	-	-	-	(17 730 405)	(238 915)	-	-	-	17 969 320	(17 318 201)
Accumulated depreciation	-	-	-	5 132 722	248 018	-	-	-	(5 380 740)	14 363 537
Depreciation charge for the year	-	(25 303 955)	(53 638 624)	(37 342 794)	(48 032 327)	(17 399 260)	(15 965 646)	-	(197 682 606)	(172 115 449)
Closing carrying amount	764 200 001	1 504 600 000	342 052 907	161 225 220	132 022 893	27 106 979	62 092 751	1 076 364	2 994 377 115	1 928 290 751
Gross carrying amount	764 200 001	1 652 532 872	521 073 146	275 951 664	310 825 372	73 693 921	95 378 197	1 076 364	3 694 731 537	2 436 343 307
Accumulated depreciation	-	(147 932 872)	(179 020 239)	(114 726 444)	(178 802 479)	(46 586 942)	(33 285 446)	-	(700 354 422)	(508 052 556)

Historical cost

	Freehold land ZWL	Buildings ZWL	Plant and machinery ZWL	Motor vehicles ZWL	Computer and equipment ZWL	Office equipment ZWL	Furniture and fittings ZWL	Work in progress ZWL	Total 2022 ZWL	Total 2021 ZWL
Opening carrying amount	140 085 601	294 437 600	73 351 176	7 380 937	10 848 344	6 823 997	10 511 045	718 692	544 157 392	62 092 523
Gross carrying amount	140 085 601	375 900 264	97 203 389	55 842 904	19 780 479	138 500 677	34 039 865	718 692	862 071 871	107 761 777
Accumulated depreciation	-	(81 462 664)	(23 852 213)	(48 461 967)	(8 932 135)	(131 676 680)	(23 528 820)	-	(317 914 479)	(45 669 254)
Additions at cost	-	-	29 822 730	44 414 765	15 094 272	4 060 947	14 523 827	357 672	108 274 213	11 037 871
Donated assets at cost	-	-	-	-	-	-	-	-	-	14 549 509
Duplicated assets	-	-	-	-	-	-	-	-	-	(73 962)
Gross carrying amount	-	-	-	-	-	-	-	-	-	(298 890)
Accumulated depreciation	-	-	-	-	-	-	-	-	-	224 928
Revaluation									2 373 903 278	463 629 199
Gross carrying amount	624 114 400	1 589 399 607	1 099 777 369	1 093 245 178	61 993 477 805	3 094 369 272	183 876 594	-	69 678 260 225	731 355 180
Accumulated depreciation	-	(371 876 267)	(852 551 400)	(975 856 502)	(61883 917 924)	(3075 862 511)	(144 292 343)	-	(67304 356 947)	(267 725 981)
Disposals carrying amount	-	-	-	(3 726 437)	(14 728)	-	-	-	(3 741 165)	(197 831)
Gross carrying amount	-	-	-	(8 108 670)	(17 242)	-	-	-	(8 125 912)	(2 333 576)
Accumulated depreciation	-	-	-	4 382 233	2 514	-	-	-	4 384 747	2 135 745
Depreciation charge for the year	-	(7 360 940)	(8 346 968)	(4 232 721)	(3 464 875)	(2 284 726)	(2 526 372)	-	(28 216 602)	(6 879 917)
Closing carrying amount	764 200 001	1 504 600 000	342 052 907	161 225 220	132 022 894	27 106 979	62 092 751	1 076 364	2 994 377 116	544 157 392
Gross carrying amount	764 200 001	1 965 299 871	1 226 803 488	1 185 394 177	62 028 335 314	3 236 930 896	232 440 286	1 076 364	70 640 480 397	862 071 871
Accumulated depreciation	-	(460 699 871)	(884 750 581)	(1024 168 957)	(61896 312 420)	(3209 823 917)	(170 347 535)	-	(67646 103 281)	(317 914 479)

Audited Financial Statement

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2022

	MCAZ GROUP				AUTHORITY			
	Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL
5 Investment property								
Opening fair value	**696 117 451**	**457 024 915**	**202 501 100**	**82 710 760**	**696 117 451**	**457 024 915**	**202 501 100**	**82 710 760**
Fair value adjustment	363 882 549	239 092 536	857 498 900	119 790 340	363 882 549	239 092 536	857 498 900	119 790 340
Closing value	**1 060 000 000**	**696 117 451**	**1 060 000 000**	**202 501 100**	**1 060 000 000**	**696 117 451**	**1 060 000 000**	**202 501 100**
6 Investment in subsidiary								
Percentage Discount (Pvt) Ltd	-	-	-	-	183 584 737	68 541 796	218 595	218 595
	-	-	-	-	**183 584 737**	**68 541 796**	**218 595**	**218 595**
7 Inventory								
Fuel	5 698 358	3 988 852	5 698 358	1 160 360	5 698 358	3 988 852	5 698 358	1 160 360
Staff provisions	4 117 665	1 113 840	1 921 337	283 313	4 117 665	1 113 840	1 921 337	283 313
Stationery consumables	111 864 534	2 018 771	7 614 226	600 364	111 864 534	2 018 771	7 614 226	600 364
	121 680 557	**7 121 463**	**15 233 921**	**2 044 037**	**121 680 557**	**7 121 463**	**15 233 921**	**2 044 037**
8 Trade and other receivables								
Trade receivables	167 269 811	120 255 005	167 269 811	34 982 273	167 269 811	120 255 005	167 269 811	34 982 273
Allowance for credit losses	(17 371 822)	(70 976 317)	(17 371 822)	(20 647 065)	(17 371 822)	(70 976 317)	(17 371 822)	(20 647 065)
	149 897 989	**49 278 688**	**149 897 989**	**14 335 208**	**149 897 989**	**49 278 688**	**149 897 989**	**14 335 208**
Other receivables	69 556 662	23 248 412	69 556 662	6 762 981	69 556 662	23 248 412	69 556 662	6 762 981
Staff receivables	123 558 624.0	-	123 558 624	-	123 558 624	-	123 558 624	-
Related party transactions-rentals	-	-	-	-	5 138 686	-	5 138 686	-
Short term investments	-	80 570	-	23 438	-	80 570	-	23 438
Tax receivable	3 375 926	259 666	3 375 926	75 537	-	-	-	-
	346 389 201	**72 867 336**	**346 389 201**	**21 197 164**	**348 151 961**	**72 607 670**	**348 151 961**	**21 121 627**
9 Cash and cash equivalents								
Bank	2 808 336 708	1 805 179 245	2 808 336 708	525 128 026	2 765 796 267	1 791 678 104	2 765 796 267	521 200 534
Funds on placement	990	1 959	990	570	990	1 959	990	570
	2 808 337 698	**1 805 181 204**	**2 808 337 698**	**525 128 596**	**2 765 797 257**	**1 791 680 063**	**2 765 797 257**	**521 201 104**
10 Deferred income								
Opening carrying amount	**416 099 495**	**353 468 745**	**15 688 367**	**2 519 382**	**416 099 495**	**353 468 746**	**15 688 367**	**2 519 382**
Balance as at January 1, 2022	461 871 811	392 413 080	17 333 735	2 784 226	461 871 811	392 413 081	17 333 735	2 784 226
Accumulated amortisation	(45 772 316)	(38 944 335)	(1 645 368)	(264 844)	(45 772 316)	(38 944 335)	(1 645 368)	(264 844)
Additions	-	69 458 731	-	14 549 509	-	69 458 731	-	14 549 509
Amortisation charge for the year	(3 718 215)	(6 827 981)	2 047 368	(1 380 524)	(3 718 215)	(6 827 981)	(2 047 368)	(1 380 524)
Closing carrying amount	**412 381 280**	**416 099 496**	**13 640 999**	**15 688 367**	**412 381 280**	**416 099 496**	**13 640 999**	**15 688 367**
Balance as at December 31, 2022	461 871 812	461 871 812	17 333 735	17 333 735	461 871 812	461 871 812	17 333 735	17 333 735
Accumulated amortisation	(49 490 532)	(45 772 316)	(3 692 736)	(1 645 368)	(49 490 532)	(45 772 316)	(3 692 736)	(1 645 368)
Analysis of carrying amount	**412 381 280**	**416 099 495**	**13 640 999**	**15 688 367**	**412 381 280**	**416 099 495**	**13 640 999**	**15 688 367**
Non- current	410 475 428	411 721 576	11 735 147	14 414 827	410 475 428	411 721 576	11 735 147	14 414 827
Amortisation charge due next year	1 905 852	4 377 919	1 905 852	1 273 540	1 905 852	4 377 919	1 905 852	1 273 540

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2022

	MCAZ GROUP				AUTHORITY			
	Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL
11 Income tax expense								
Current tax					-	-	-	-
Current tax	1 258 576	1 664 076	1 258 576	484 081	-	-	-	-
Deferred tax	-	(243 322)	-	(70 783)	-	-	-	-
	1 258 576	1 420 754	1 258 576	413 298	-	-	-	-
11.1 Tax reconciliation					-	-	-	-
Profit before tax	5 091 327	6 731 698	5 091 327	1 958 256	-	-	-	-
Notional tax thereon at a rate of 24.72%	1 258 576	1 664 076	1 258 576	484 081	-	-	-	-
Permanent differences	-	(243 322)	-	(70 783)				
	1 258 576	1 420 754	1 258 576	413 298				
11.2 Current tax liability/asset								
Balance as at 1 January 2022	(75 538)	(205 229)	(75 538)	(59 702)	-	-	-	-
Current year charge	1 258 576	1 664 076	1 258 576	484 081	-	-	-	-
Payments	(4 558 964)	(1 718 517)	(4 558 964)	(499 918)	-	-	-	-
Balance as at 31 December 2022	(3 375 926)	(259 670)	(3 375 926)	(75 539)				
11.3 Deferred tax					-	-	-	-
Balance at 1 January 2022	48 677 603	24 810 171	14 160 350	7 217 298	-	-	-	-
Deferred tax recognised through profit and loss	-	(243 322)	-	(70 783)	-	-	-	-
Deferred tax recognised through other comprehensive income	21 201 175	4 699 158	81 090 398	1 366 989	-	-	-	-
Deferred tax recognised directly in equity	72 523 543	19 411 596	52 746 750	5 646 848	-	-	-	-
Net deferred tax liability	142 402 321	48 677 603	147 997 498	14 160 352	-	-	-	-
12 Trade and other payables								
Trade payables	92 677 146	65 197 006	92 677 146	18 965 859	92 677 146	65 197 006	92 677 146	18 965 859
Sundry payables	62 909 484	67 455 594	62 909 484	19 622 884	58 186 880	67 455 594	58 186 880	19 622 884
Other payables	317 142 234	250 470 237	317 142 234	72 861 984	317 027 961	250 451 561	317 027 961	72 856 551
Unallocated income	8 177 997	13 479 789	8 177 997	3 921 281	8 177 997	13 479 789	8 177 997	3 921 281
	480 906 861	396 602 626	480 906 861	115 372 008	476 069 984	396 583 950	476 069 984	115 366 575
13 Provisions								
Leave pay provision	10 154 493	13 248 508	10 154 493	3 854 001	10 154 493	13 248 508	10 154 493	3 854 001
14 Medicines control income								
Amendment fees	72 847 956	60 374 423	50 756 315	13 594 249	72 847 956	60 374 423	50 756 315	13 594 249
Clinical trials	20 273 511	14 106 597	15 289 746	3 417 566	20 273 511	14 106 597	15 289 746	3 417 566
Dangerous drugs license	76 317 851	191 635 817	41 290 592	42 967 825	76 317 851	191 635 817	41 290 592	42 967 825
Drug registration and forensic examination	3 622 053	1 279 601	2 729 228	304 733	3 622 053	1 279 601	2 729 228	304 733
Import and export licenses	360 678 110	232 909 012	252 166 530	53 646 003	360 678 110	232 909 012	252 166 530	53 646 003
Inspection	360 650 068	162 076 438	262 474 172	37 328 971	360 650 068	162 076 438	262 474 172	37 328 971
Persons and premises licenses	144 577 096	87 568 532	96 483 866	19 753 083	144 577 096	87 568 532	96 483 866	19 753 083
Registration fees	416 146 090	262 320 997	275 784 756	62 394 335	416 146 090	262 320 997	275 784 756	62 394 335
Renewal of licenses	264 264 712	135 604 256	100 810 721	28 455 919	264 264 712	135 604 256	100 810 721	28 455 919
Retention fees	540 905 623	355 948 780	381 946 462	81 056 732	540 905 623	355 948 780	381 946 462	81 056 732
Sales representatives and wholesale dealers	28 590 210	21 378 490	18 430 493	4 850 491	28 590 210	21 378 490	18 430 493	4 850 491
Unregistered medicines	100 601 995	73 485 382	74 961 254	16 664 118	100 601 995	73 485 382	74 961 254	16 664 118
Veterinary permits	20 436 388	19 532 021	10 124 621	3 940 673	20 436 388	19 532 021	10 124 621	3 940 673
	2 409 911 663	1 618 220 346	1 583 248 756	368 374 698	2 409 911 663	1 618 220 346	1 583 248 756	368 374 698
15 Laboratory services income								
Condom testing	77 789 472	12 150 985	60 945 285	2 816 008	77 789 472	12 150 986	60 945 285	2 816 008
Glove testing	13 418 483	12 272 281	9 852 428	3 065 882	13 418 483	13 724 271	9 852 428	3 065 882
Medical devices-registration	-	1 451 990	-	-	-	-	-	-
Samples - external clients	444 473 569	293 250 695	336 497 581	71 670 623	444 473 569	293 250 695	336 497 581	71 670 623
	535 681 524	319 125 951	407 295 294	77 552 513	535 681 524	319 125 952	407 295 294	77 552 513

	MCAZ GROUP				AUTHORITY			
	Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL
16 Other income								
Amortisation for the year	3 718 215	6 827 981	2 047 368	1 380 524	3 718 215	6 827 981	2 047 368	1 380 524
Decrease in provision for leave pay	3 094 015	-	-	-	3 094 015	-	-	-
Donations	84 298 017	36 362 376	68 438 128	9 005 505	84 298 017	36 362 376	68 438 128	9 005 505
Interest earned	5 323 816	30 715	4 534 870	7 440	5 323 816	4 699	4 534 870	966
Rentals	90 681 784	61 142 596	64 571 861	13 998 024	68 594 611	49 415 497	48 479 840	11 330 995
Fair value adjustment	363 882 549	239 092 536	857 498 900	119 790 340	363 882 549	239 092 536	857 498 900	119 790 340
Sundry income	60 831 850	14 172 830	39 843 459	5 848 472	60 831 505	14 172 830	39 843 260	5 848 472
Realised gain on disposed asset	-	10 672 107	-	193 126	-	10 672 107	-	193 126
Exchange gain/loss realised	1 135 016 047	38 882 768	1 115 862 295	10 742 302	1 107 248 822	35 847 712	1 088 095 070	9 859 402
Exchange gain/loss unrealised	1 087 282 314	290 669 592	1 068 474 724	84 556 007	1 087 282 314	290 669 592	1 068 474 724	84 556 007
Decrease in provision for credit losses	67 701 098	-	3 275 243	-	67 701 098	-	3 275 243	
	2 901 829 705	**697 853 501**	**3 224 546 848**	**245 521 740**	**2 851 974 962**	**683 065 330**	**3 180 687 403**	**241 965 337**
17 Administration expenses								
Audit fees	7 915 292	7 692 520	3 856 753	1 781 379	7 228 271	7 198 097	3 522 000	1 680 000
Board fees	55 986 004	41 255 515	46 710 711	10 237 736	52 674 139	40 698 133	44 091 234	10 110 398
Bank charges	82 053 897	26 369 126	64 566 709	6 182 808	81 714 497	26 132 568	64 311 090	6 127 038
Communications	11 793 396	8 563 790	8 852 694	1 900 784	11 793 396	8 563 790	8 852 694	1 900 784
Consumables	14 133 481	10 190 193	11 420 144	2 220 910	14 133 481	10 190 193	11 420 144	2 220 910
Credit losses	-	98 687	-	28 708	-	98 687.00	-	28 708
Depreciation for the year	206 328 801	173 605 026	36 817 109	7 223 148	197 682 606	172 115 449	28 216 602	6 879 917
General administration	181 854 750	87 265 184	140 473 719	16 409 213	181 854 750	87 063 872	140 473 719	16 366 588
Increase in provision for leave pay	-	9 370 821	6 300 492	3 152 231	-	9 370 821	6 300 492	3 152 231
Increase in provision for credit losses	-	70 632 121	-	20 584 773	-	70 632 121	-	20 584 773
Inspections	178 969 009	37 924 108	129 877 035	8 936 314	176 112 946	36 322 892	127 812 771	8 545 525
IT expenses	79 677 681	35 927 709	65 129 093	8 368 564	79 677 681	35 927 709	65 129 093	8 368 564
Legal and professional fees	19 663 371	16 573 105	12 100 897	3 808 499	19 663 371	16 573 105	12 100 897	3 808 499
Printing and stationery	36 220 287	17 369 401	27 632 594	4 206 031	36 220 287	17 369 401	27 632 596	4 206 031
Loss on disposal of property,plant and equipment	10 232 020	673 216	3 564 649	173 581	10 232 020	673 216	3 564 649	173 581
Public relations	27 801 670	5 871 514	24 169 780	1 419 610	27 801 670	5 871 514	24 169 781	1 419 610
Quality assurance costs	1 866 677	6 881 553	1 820 387	1 589 832	1 866 677	6 881 553	1 820 387	1 589 832
Rates, electricity and water	19 059 746	13 774 670	14 786 685	3 206 045	19 059 746	13 774 670	14 786 683	3 206 045
Repairs and maintenance	76 010 820	25 970 189	55 174 488	6 126 256	70 872 134	25 970 189	50 035 802	6 126 256
Security and insurance costs	27 148 800	18 066 044	21 486 562	4 465 991	26 807 200	17 828 492	21 241 701	4 411 753
Strategic planning	92 280 995	35 513 509	83 084 850	9 209 913	92 280 995	35 513 509	83 084 850	9 209 913
Subscriptions	18 940 335	10 717 565	13 512 005	2 380 541	18 940 335	10 717 565	13 512 005	2 380 541
Travelling and subsistence	12 269 543	4 945 759	9 677 880	1 080 255	12 269 543	4 945 759	9 677 880	1 080 255
Vehicle running costs	36 234 701	33 418 269	25 173 134	7 912 787	36 234 701	33 418 269	25 173 134	7 912 787
	1 196 441 276	**698 669 594**	**806 188 370**	**132 605 909**	**1 175 120 446**	**693 851 574**	**786 930 204**	**131 490 539**

	MCAZ GROUP				AUTHORITY			
	Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL	2022 ZWL	2021 ZWL
18 Other expenses								
Salaries and wages	1 473 185 149	918 360 636	1 056 600 513	217 991 590	1 473 185 149	918 360 636	1 056 600 513	217 991 590
Pension and medical aid	175 448 818	107 734 811	119 786 286	25 102 827	175 448 818	107 734 811	119 786 286	25 102 827
Staff training expenses	37 767 913	8 796 790	29 198 943	2 174 570	37 767 913	8 796 790	29 198 943	2 174 570
Staff welfare	30 578 759	20 540 008	25 040 323	4 945 448	30 578 759	20 540 008	25 040 323	4 945 448
	1 716 980 639	**1 055 432 245**	**1 230 626 065**	**250 214 435**	**1 716 980 639**	**1 055 432 245**	**1 230 626 065**	**250 214 435**
19 Related party transactions								
The remuneration of the Board members and other key management personnel during the financial year were as follows:								
19.1 Board members benefits	8 462 487	3 083 711	6 823 306	655 313	8 349 954	3 083 711	6 722 186	655 313
Board members fees	55 417 669	38 729 186	39 988 525	9 582 423	52 674 139	38 171 804	37 369 048	9 455 085
	63 880 156	**41 812 897**	**46 811 831**	**10 237 736**	**61 024 093**	**41 255 515**	**44 091 234**	**10 110 398**
19.2 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								
Director- General benefits	9 440 912	5 418 457	2 251 453	489 130	9 440 912	5 418 457	2 251 453	489 130
Director-General salary	49 042 449	31 187 998	35 689 740	7 036 601	49 042 449	31 187 998	35 689 740	7 036 601
	58 483 361	**36 606 455**	**37 941 193**	**7 525 731**	**58 483 361**	**36 606 455**	**37 941 193**	**7 525 731**

20 Pension arrangements

20.1 Defined contribution plan

The Authority operates a defined contribution plan administered by ZIMNAT. The scheme is a post-employment benefit plan under which the Group pays fixed contributions into a separate entity and has no legal or constructive obligation to pay further amounts. 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. Employees are members of the ZIMNAT Pension Fund to which the Group contributes 15% while employees contribute 7.5% of pensionable emoluments.

During the year under review, pension fund contributions amounted to ZWL 18 666 571 (2021: ZWL 2 646 500)

20.2 National Social Security Authority (NSSA)

The National Social Security Authority was introduced on October 1, 1994 and with effect from that date all employees are members of the scheme to which both the Authority and its employees contribute as follows:

Employees: 4.5% of the monthly basic salary
Authority: 4.5% of the monthly basic salary

The amount charged through the statement of profit or loss during the year under review amounted to ZWL 21 322 597 (2021: 9 149 162)

Licensing and Enforcement

In 2022, the Licensing and Enforcement Division continued to execute its duties through the following activities, and more:

- Licensing of premises
- Licensing of persons
- Authorisations for Importation of Unregistered Medicines
- Screening and Authorisation of Donations
- Control of the Import and Export of Narcotics
- Inspections of licensed and unlicensed premises
- Import and Export Control
- Collaboration with law enforcement agents to monitor unlawful sale and distribution of medicines
- Collaboration with ZIMRA and Port Official in clearing medicines and ports of entry

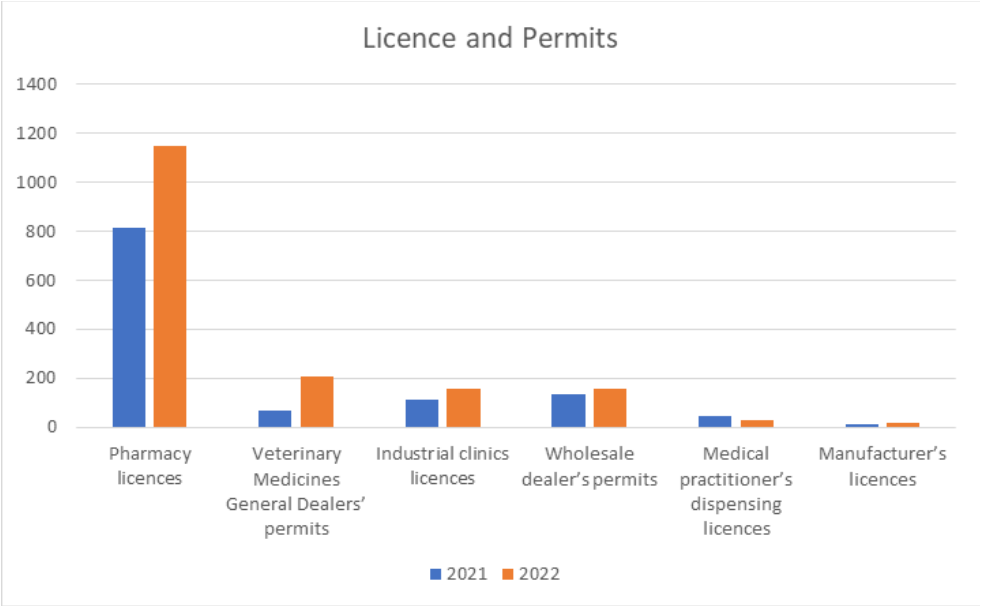
Licensing

Table 1

Licensing of premises

Licenses and Permits	**2021**	**2022**
Pharmacy licences	815	1146
Veterinary Medicines General Dealers' permits	70	207
Industrial clinics licences	111	155
Wholesale dealer's permits	134	157
Medical practitioner's dispensing licences	45	30
Manufacturer's licences	13	16

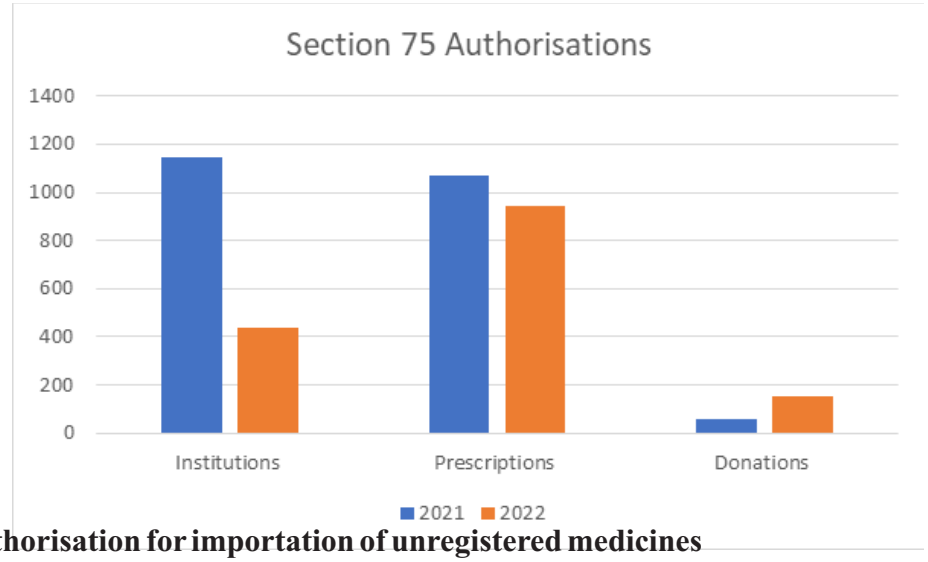
Graph 1: Licensing of premises



2022 witnessed a significant increase in applications for pharmacy licences and veterinary medicines general dealers permits as well as industrial clinic licences. There was however a decline in licences issued for dispensing medical practitioners. New manufacturers were licenced in 2022.

Table 2: Authorisation for importation of unregistered medicines

Section 75	**2021**	**2022**
Institutions	1148	438
Prescriptions	1067	944
Donations	56	154



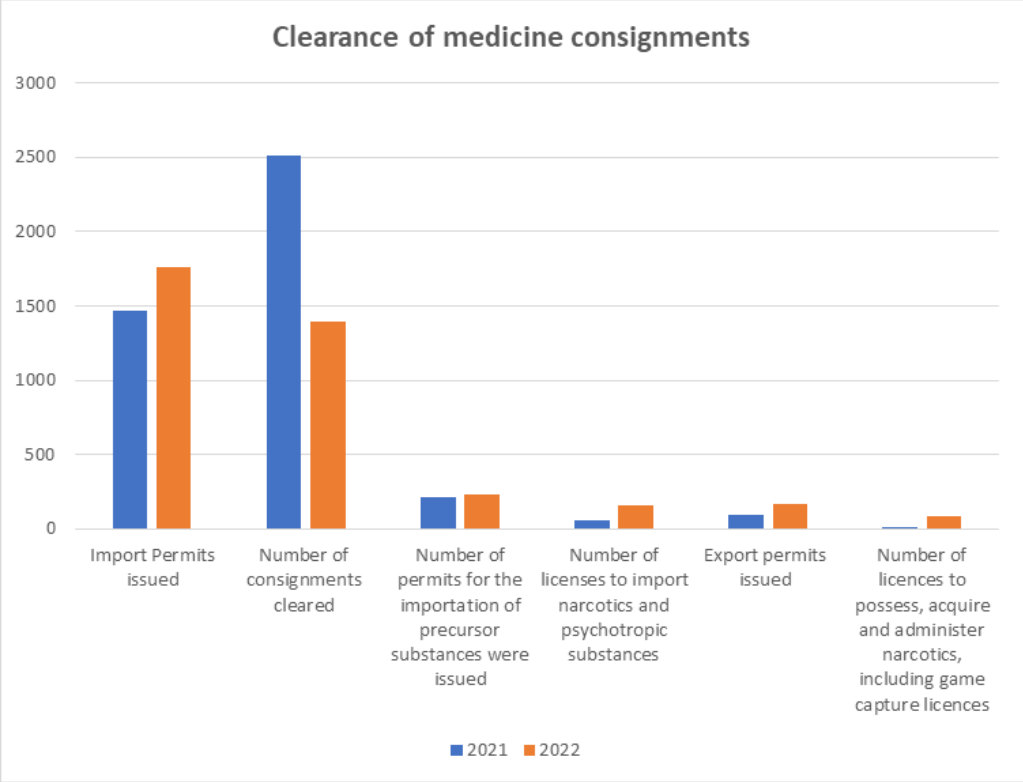
Graph 2: Authorisation for importation of unregistered medicines

Licensing and Enforcement

2022 had a significant decline in the number of Section 75 applications received and processed for institutions. There was however slight change on applications processed for individual prescriptions. The relative importation of unregistered products can be attributed to the implementation of Circular 23 and 24 of 2022 which controlled import of medicines in bulk through parallel importation.

Table 3: Clearance of medicine consignments

Administrative issues	2021	2022
Import Permits issued	1465	1758
Number of consignments cleared	2509	1394
Number of permits for the importation of precursor substances were issued	210	233
Number of licenses to import narcotics and psychotropic substances	57	162
Export permits issued	94	170
Number of licences to possess, acquire and administer narcotics, including game capture licences	14	90



Graph 3: Clearance of medicine consignments

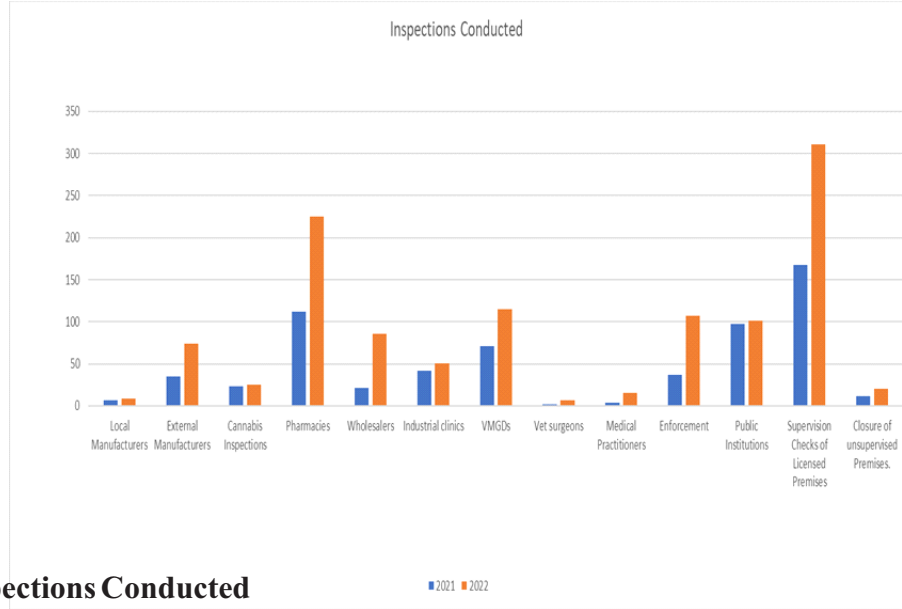
Licensing and Enforcement

There was a significant decrease in the number of consignments cleared in 2022 owing to the decrease in Covid cases that had given rise to the need for more consignment in the year 2021. Import permit applications were sightly increase when compared to 2021. The increased number of licences for narcotic and pyschotropic licence could be attributed to new licences for the importation of Cannabis seed for production. 2022 witnessed a significant increase in export permits which was almost double the number of permits issued in 2021.

Enforcement

Table 4: Inspections conducted

Premises Type	2021	2022
Local Manufacturers	7	9
External Manufacturers	35	74
Cannabis Inspections	23	25
Pharmacies	112	225
Wholesalers	21	86
Industrial clinics	42	51
VMGDs	71	115
Vet surgeons	2	7
Medical Practitioners	4	15
Enforcement	37	107
Public Institutions	97	101
Supervision Checks of Licensed Premises	168	311
Closure of unsupervised Premises.	12	20



Graph 4: Inspections Conducted

Inspections for all premises started to increase in 2022 after a significant decline in activities in 2021 due to Covid -19. Double the amount of premises were inspected in 2022 when compared 2021. Only public institution inspection maintained more or less the same number as these premises inspection

were never affected by Covid-19 lock down and sampling and inspections were done in accordance with the plans.

Good Manufacturing Practice Inspections

Following the Global Benchmarking Tool requirements, Inspectorate managed to inspect all local manufacturers for compliance with Good Manufacturing Practices in 2022. A number of Quality Circle meetings were held with local manufacturers to address areas where common gaps had been noted during inspections. External manufacturers were also inspected in line with their volume of imported products on a risk based approach. A number of premises had become due for inspection post Covid -19 lock down and travel restrictions.

Good Supply and Distribution practice inspections

All wholesale dealers were inspected prior to renewal of premises permits in line with GBT requirements. This also followed the need to assess for compliance with the updated Good Supply and Distribution Practices (GSDP) Guidelines. The Authority managed to hold stakeholders training for the wholesalers on areas of concern especially the need to comply with quality management systems for medicine that was not in the previous guidelines.

Compliance to ISO 17020 and WHO Global Bench Marking

The Division continued to maintain its compliance status with ISO 17020 requirements.
Following the 2021 WHO assessment division continued to work on addressing IDPs raised
Automation and optimization of key processes

The Division has been automating most of its key processes since 2018 and the following processes are fully functional with on-going validations:

1. Import and Export application process
2. Section 75 application process for unregistered medicines
3. Licences and Permits applications for premises and persons
4. Narcotic Licences

Lessons learnt and plans for the future

1. In the period under review the inspectorate faced significant staff attrition which also affected the processes due to the hyperinflationary environment.
2. The Division hopes to achieve WHO Global Benchmark Level 3 by end of year 2023.

MEDICINAL CANNABIS IN ZIMBABWE

Background

The Dangerous Drugs Act [Chapter 15:02] is an Act that provides for the control of the importation, exportation, production, possession, sale, distribution and use of dangerous drugs; and to provide for matters incidental thereto. In terms of Section 6 of the Dangerous Drugs Act [Chapter 15:02], the Minister of Health and Child Care published the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2018 [*S.I 62 of 2018*]. Only producers licensed in terms of the S.I. 62 of 2018 are allowed to handle Cannabis from their licensed cannabis cultivation sites.

The Licensing and Enforcement – Cannabis Desk was then formed in 2018 to administer the S.I. 62 of 2018 on behalf of the Ministry of Health and Child Care. This encompasses matters pertaining to new applications for licences 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 fifty-nine (59) production of Cannabis for medicinal and scientific use licences have been issued to date. Fifty-eight licences are currently active with (56) licences being for cultivation and production and two (2) cultivation and research licences. The first licence was issued in 2019.

Cannabis licences issued.			
2019	2020	2021	2022
35	12	10	2

MEDICINAL CANNABIS IN ZIMBABWE

General summary of all Cannabis cultivation sites

Cannabis cultivation site level of description	Number
Number of sites with Cannabis cultivation sites witnessed during inspection	5
Number of sites focusing on Industrial Hemp in the interim with plants witnessed during inspections	4
Number of sites visited with no development activities yet	18
Number of sites with construction activities in progress	11
Sites that are licensed but are still to be inspected by MCAZ, some of which the licensed sites are not known by the Authority	14
Number of sites with research licences and focusing on Industrial Hemp research	2
Number of surrendered licences	1
Total Number of licences issued	**59**

Measures put in place by the Authority inorder to promote ease of doing business in the Cannabis Industry

The Authority has an open-door policy to stakeholders and has in the past years been involved in a number of stakeholder engagements inorder to clarify the regulatory requirements, case in point the Cannabis Round Table, 2022. In 2022 the Authority also conducted stakeholder engagements in a bid to revise the Statutory Instrument 62 of 2018, so that it meets the expectations of the industry as well as to clarify some provisions which were previously vague. The draft amendment is pending approval by the Minister of Health and Child Care. In 2022 the Authority also initiated the formation of Cannabis working groups with other stakeholders like the Agricultural Marketing Authority in a bid to streamline activities. The Authority has also initiated the formation of a cannabis inspectorate team which is responsible for monitoring compliance to the set statutes and licensing requirements. There was also formation of a Controlled Substances Committee whose role is to make decisions on all issues related to Cannabis licensing and production.

MEDICINAL CANNABIS IN ZIMBABWE

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

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

Two (2) processing sites have submitted applications for manufacturing licences in 2022. Both applicants were inspected in the first quarter of 2023, and one (1) of the companies has been issued with a pharmaceutical manufacturer's licence restricted to complementary medicines manufacture.

Evaluations and Registration Division

Introduction

The Evaluations & Registration Division (EVR) is responsible for 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.

Activities

Focus on notable changes and developments.

To improve timelines and to remove products from non-responsive applicants, the Division assigned application tracking to a dedicated administrator. This process stimulated applicants to respond on time and resulted in the closure of 68 applications from non-responsive applicants. Removing such applications made modest improvements to the very full pipeline of pending applications for registration.

Human allopathic medicines

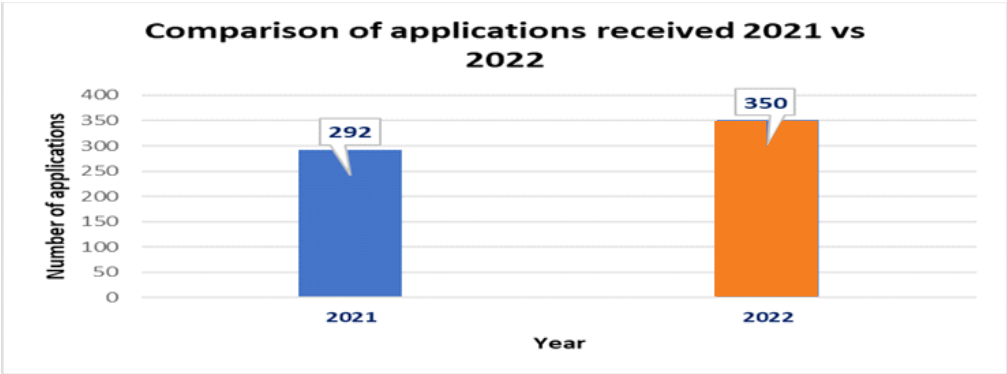
Highlights

Applications for Registration

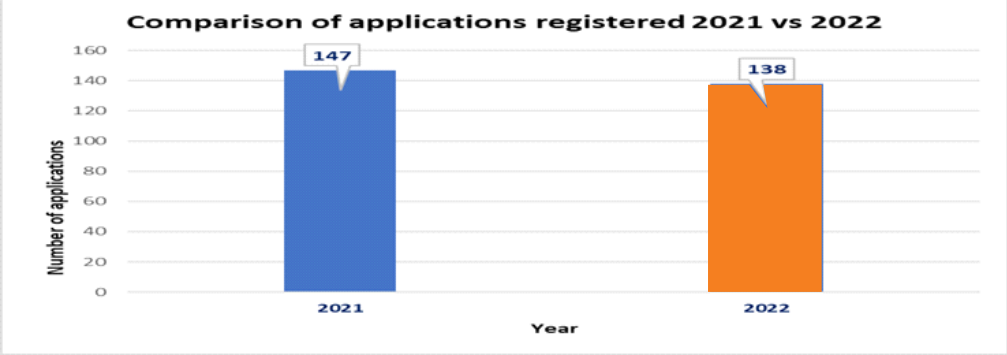
Received	Registered	Refused	Withdrawn
350	138	59	7

The Division recorded a 11% increase in revenue collected from applications for externally manufactured products and 235% increase in revenue collected from applications for locally manufactured products in 2022. The increases in revenue can be attributed to an increase in applications for registration as well as the economic adjustments in local fees due to inflation. Out of the 256 applications for registration of medicines that were assessed in 2022, 138 were registered. The online register for approved human medicines is available on MCAZ website and the register is updated in real-time.

Trend analysis (2021 vs 2022)



Graph 5 shows 20% increase in applications for registration received in 2022.



Graph 6 shows 7% decrease in applications registered in 2022.

Post-Approval Variations

Variations Received	Variations Processed	Variation Responses Received	Variation Responses Processed
480	460	266	189

The Division processed 96% of the variations to registered human medicines that were received in 2022. Furthermore, 71% of the responses to variations received were processed in the same period.

Veterinary medicinal products

Highlights

Applications for Registration

Received	Registered	Refused	Withdrawn
15	12	0	0

Evaluations and Registration Division

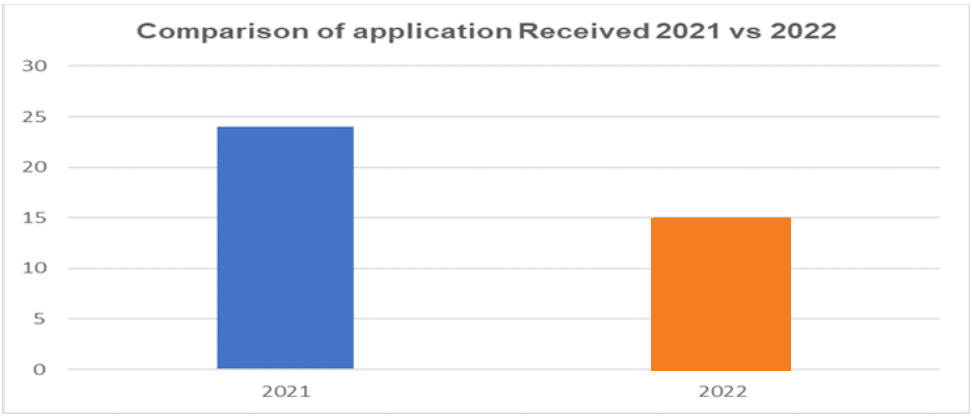
Out of the 25 applications for registration of medicines that were assessed in 2022, 12 were registered. The online register for approved veterinary medicines is available on MCAZ website and the register is updated in real-time. In addition, five veterinary complementary medicines were assessed and approved in 2022. Furthermore, six dipping trial protocols were assessed and approved during the same year.

Post-approval Variations

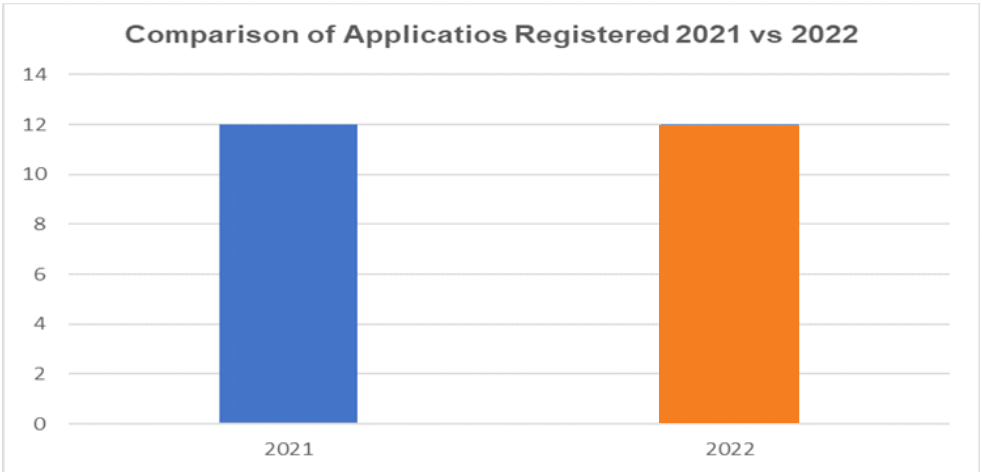
Variations Received	Variations Processed	Variation Responses Received	Variation Responses Processed
55	36	26	20

The Division processed 65% of the variations to registered veterinary medicines that were received in 2022. Furthermore, 78% of the responses to variations received were processed in the same period.

Trend analysis (2021 vs 2022)



Graph 7 shows 38% decrease in applications for registration received in 2022.



Graph 8 shows no % increase in applications registered in 2022.

Evaluations and Registration Division

Complementary Medicines

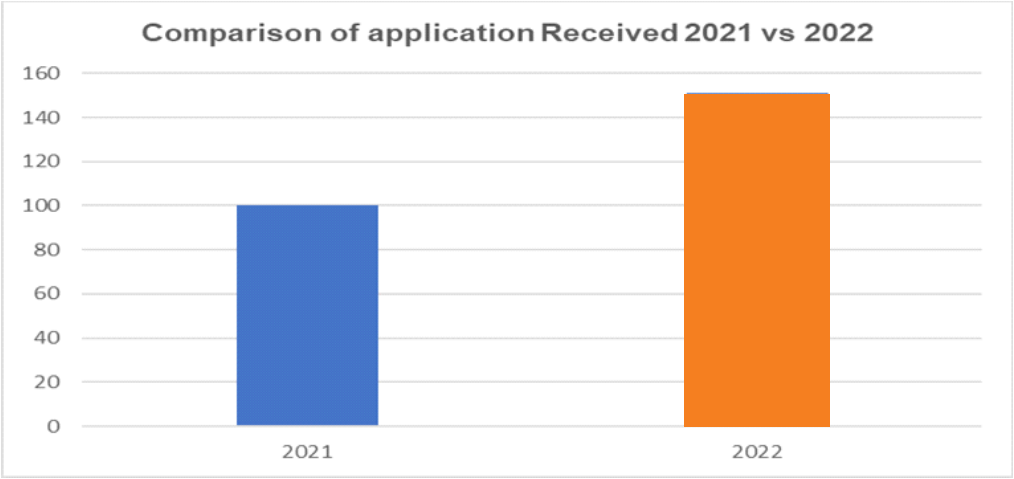
Highlights

Applications for approval

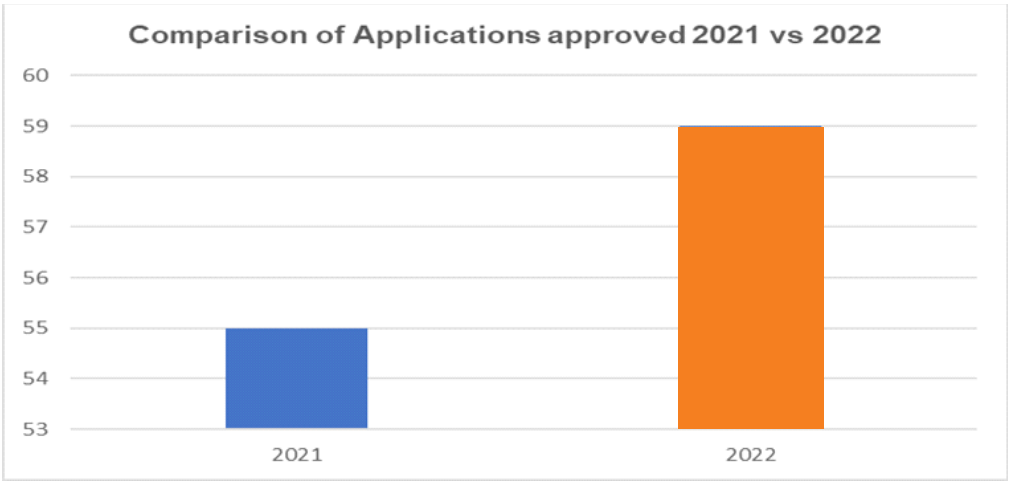
Received	Approved	Refused	Withdrawn
151	59	0	0

Out of the 76 applications for approval of complementary medicines that were assessed in 2022, 57 were registered. The online register for approved complementary medicines is available on MCAZ website and the register is updated in real-time.

Trend analysis (2021 vs 2022)



Graph 9 shows 51% increase in applications for approval of complementary medicines received in 2022.



Graph 10 shows 7% increase in applications for registration received in 2022.

Zazibona

The division continued to coordinate assessments of dossiers at the SADC level under the Zazibona collaboration. In 2022, four (4) assessment sessions were held and forty-one (41) new products were assessed under the Zazibona collaboration. Physical joint assessment sessions which had stopped at the height of the Covid-19 pandemic were also resumed. As at the end of 2022, 378 products had been assessed under the Zazibona collaboration since it's inception in 2013. Of these 378 products, 321 had been finalised.

Key/notable achievements

Senior assessors of the Division continued providing support through the Authority's Small Business Support Unit. The Division continued providing advice on technical requirements on registration of products to existing as well as greenfield projects to local applicants in line with the NDS1 2021 to 2025 and the Pharmaceutical Manufacturing Strategy 2021 to 2025. These facilitative regulatory processes being offered by the Division are part of the Authority's efforts to support local industry in improve the local production of medicines, thereby increasing the availability of the country's essential medicines and exporting excess products.

In addition, the Division started accepting applications for registration of Hem-based Cannabidiol (CBD) as complementary medicines starting second quarter 2022. In its circular dated July 2022, the Authority listed requirements based on the existing complementary medicines guidelines providing detailed guidance to licensed cannabis/hemp producers, manufacturers, importers or exporters and retail pharmacists.

Furthermore, the Division was able to finalise draft Medicated Feeds Regulations which had been under stakeholder consultation for 2 years in December 2022. A stakeholder consultative validation meeting was held on the 12th December 2022 at Holiday Inn Hotel, Harare to validate and finalise the Regulations before they were submitted to the Minister of Health and Child Care for final approval.

Lessons learnt and Challenges

The Division had to grapple with the loss of 7 experienced staff members, with technical experience ranging from 3 years to 24 years. This loss of skill made adhering to EVR process timelines particularly challenging.

Zazibona

Plans for the future.

In spite of the challenges, EVR hopes to attain WHO Global Benchmarking Tool (GBT) maturity level 3 for the regulatory function of market authorization (registration). (Maturity level 3 is defined as a stable, well-functioning, and integrated regulatory system). The division has been working towards closing all the gaps/deficiencies identified by the WHO GBT assessors during the initial benchmarking assessment.

Pharmacovigilance and Clinical Trials Division

Introduction

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. All clinical trials of medicines in Zimbabwe involving human participants must not be conducted until the MCAZ has, with the approval of the Secretary for Health and Child Welfare, 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 for the purpose of conducting clinical trials. Any amendments required during the conduct of the study, must be approved by MCAZ. The MCAZ was also 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 of this, the MCAZ through the Pharmacovigilance and Clinical Trials division designed an intensive course to build capacity and equip regulators in clinical trials and pharmacovigilance.

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 drug safety such as unknown or poorly characterized adverse events in relation to a drug 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 partners. Through the National Pharmacovigilance Centre, which is housed in the Pharmacovigilance and Clinical Trials (PVCT) division the MCAZ also undertakes assessment of 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 Bench Marking Tool Version VI currently expanded the scope of pharmacovigilance to include safety monitoring of all types medical products to include vigilance regulation function such medicines, vaccines, haemovigilance(blood products and its components safety monitoring).

Pharmacovigilance and Clinical Trials Division

The Pharmacovigilance and Clinical Trials (PVCT) division is responsible for the following functions;

i. Authorisation and monitoring of all clinical trials involving medicines and medical devices that are conducted in Zimbabwe in terms of Part III of the Medicines and Allied Substances Control Act of 1991 [Chapter 15:03].

ii. Processing of post-registration safety variations and applications for promotional materials.

iii. The national centre for pharmacovigilance which conducts safety monitoring of medicines, and vaccines vigilance regulatory functions in collaboration with the Ministry of Health and Child Care public health programs, private health sectors, healthcare providers, pharmaceutical industry, consumers, patients and partners including vigilance indicators as defined in the WHO Global Bench Marking Tool(GBT) 2018 version VI . This includes medicines (ADRs/SAEs), vaccines (AEFIs) safety monitoring, haemovigilance, causality assessment including benefit/risk analysis, and communication in a way that improves therapeutics and risk minimisation.

iv. Medicine, vaccines and haemovigilance information dissemination through publishing medicine information bulletin, manuscripts publications, circulars, and alert notices.

v. Processing retentions fees for registered medicines both human products and veterinary products.

vi. Medicines safety reviews and re-categorisations.

vii. 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.

Activities

Clinical trial activities

In accordance with MASCA Chapter 15:03 section 16, clinical trials of medicines and vaccines in humans require clinical trial protocol applications and subsequent protocol amendments to be submitted to the MCAZ for evaluation and authorisation by the Secretary for the Ministry of Health and Child Care (MoHCC). This includes monitoring of the approved clinical trials by MCAZ for compliance with good clinical practice (GCP) including GCP inspections, clinical trial protocol amendments approvals, protocol deviations reporting, safety reports, submission of preliminary and final reports/publications. In addition, for clinical trial monitoring purposes and in line with the conditions of authorization of clinical trials, serious adverse event (SAEs) reports, progress reports and final reports for authorized clinical trials should be submitted to MCAZ. Ten (10) clinical trial applications were received in 2022, an increase from nine (9) new clinical trial applications received in

2021. All the clinical trials received in 2022, were submitted and processed using the electronic-Clinical Trials Application and Registry (e-CTR) system. Of the 10 clinical trials received in 2022, four (4) were for HIV prevention and management, four (4) were for COVID-19 prevention and management, one was for contraception and one application was for tuberculosis treatment. All the applications received were processed within the target timelines of 60 working days and 15 working days for the expedited review applications. Six (6) Good Clinical Practice (GCP) inspections were conducted in 2022, with four (4) being routine inspections, one (1) being a triggered inspection and one (1) being a re-inspection. 158 Individual Case Safety Reports (ICSRs) were received from various authorized clinical trials in 2022, and these accounted for 37.6% of all ICSRs received by MCAZ in 2022.

A total of US$30 344.35 was generated from clinical trials activities against an annual target of US$30 000. The table below shows various clinical trial monitoring reports which were received and processed in 2022.

Table 1: Clinical trial monitoring submissions processed from 1 January 2022 to 31 December 2022

Type of report	Number of reports received	Number of reports processed
Clinical trial protocol amendments	39	39
DSMB reports, Progress reports and Final reports,	83	74*
Applications for the importation of investigational products	97	97
Protocol deviation report	103	114**

* 9 reports were carried over to 2023 as they were submitted towards the end of the year after the last PVCT Committee meeting.

** 11 protocol deviation reports were brought forward from 2021

Medicines Vigilance

202 ADRs were received in 2022 from consumers, public Ministry of Health and Child Care sites, private sector clinics, hospitals, and pharmacies and these accounted for 48% of the Individual Case Safety Reports (ICSRs) reports received by MCAZ in 2022. Of these ADR reports, 129 reports involved antiretroviral medicines as suspected /concomitant medicines, 54 reports involved anti-tuberculosis medicines and 19 reports involved other essential medicines. These reports were all

uploaded onto the MCAZ electronic pharmacovigilance (e-PV) system, processed for causality assessment by the national PVCT Committee, feedback provided to the reporters, and anonymized reports uploaded to the WHO VigiBase database. The e-PV system is an electronic platform for reporting adverse drug reactions, with both online and offline reporting capabilities and it is accessible via the following hyperlink: https://e-pv.mcaz.co.zw/users/login For detailed guidance on how to navigate and utilize the e-PV system, users can refer to the Pharmacovigilance Electronic User Manual which is accessible via the following link: https://www.mcaz.co.zw/wp-content/uploads/2021/12/e-PV-External-User-Manual-Revision-0_June-2020.pdf

All feedback letters were provided to the reporters and relevant medicine information bulletin articles made.. There was a slight decrease in the number of reports received in 2022 (202 reports) compared to 2021 (235 reports). Reports tend to increase when pharmacovigilance trainings are done.

ADR and SAE reports can also be submitted by consumers via the online consumer reporting link which is accessible via the following link: https://primaryreporting.who-umc.org/ZW

An overview of all individual case safety reports received by MCAZ in 2022 is shown in the table on next page:

Table 2: Overview of Individual Case Safety Reports (ICSRs) (ADRs, AEFIs & SAEs) reports received by MCAZ in 2022

Type of report	Number received	Percentage of total ICSRs	Comments and PVCT Committee causality assessment outcome summaries.
ADRs and SAEs received from pharmaceutical Industry	33	7.8%	There was a decrease in the number of ICSR received from pharmaceutical industry in 2022 as compared to 2021 (57 reports). ADRs and SAEs are received from pharmaceutical industry as and when they occur.
Adverse Events Following Immunization (AEFIs)	28	6.7%	There was a decrease in the number of AEFI reports received in 2022 as compared to 2021 whereby 445 reports were received. Stimulated reporting through the STARSS project contributed to the high number of reports received in 2021 and the STARSS sites had closed to accrual in 2021. In 2021, there were more COVID-19 vaccinations compared to 2022 and AEFI surveillance refresher trainings were conducted in 2021 for all the provinces in Zimbabwe following the introduction of the COVID-19 vaccination programme in Zimbabwe in February 2021. Among the 445 AEFI reports received in 2021, 311 were from the COVID-19 vaccinations.
ADRs from the TSR of all essential medicines including ARVs and Anti-TBs from public MoHCC sites and some private sector clinics and doctors.	202	48%	There was a slight decrease in the number of ADR reports received in 2022 as compared to 2021 (235). Reports tend to increase if there are provincial pharmacovigilance training programs done. In 2021, 24 sites were trained on medicines vigilance compared to 20 sites in 2022.
Serious Adverse Events(SAEs) from approved clinical trials conducted in Zimbabwe.	158	37.5	The SAEs reports from approved clinical studies where successful case management was done by the medical doctor researchers. These are closely monitored as it is a mandate for principal investigators to report the SAEs. An increase in SAEs received from clinical

Pharmacovigilance and Clinical Trials Division

Causality assessment is defined as finding a causal association or relationship between a medicine and a medicine reaction. 45% of the ADR reports received in 2022 were serious whereas 55% were non-serious. The causality assessment for (91%) of the ADR reports, was either probable or possible which means most reactions were likely to have been attributed to the suspected medicines. In 27% of these reports, it was indicated that the patients had recovered or were recovering from the adverse drug reactions. The outcome in 33% of these reports however was indicated as unknown. 52% of the AEFI reports received were serious and 48% were non-serious. For 27% of the serious AEFIs reports, the vaccine recipients recovered and for 71% of the non-serious AEFI reports, the vaccine recipients recovered. For 66% of the total AEFI reports received in 2022, the causality assessment was A1 and A4 which meant that the adverse events were related to the suspected vaccine or the vaccination process. For SAE reports from clinical trials, causality assessment for 56% of submitted reports resulted in a classification of unlikely, which reflects that the adverse events could likely be attributed to other causes. 29% of the submitted reports had a classification of either probable or possible but all reactions were appropriately managed and participants were recovering and it was noted that most of the adverse reactions were those already associated with the medicines which were routinely given as standard of care. For ADRs from pharmaceutical industry, 39% of the reports were assigned a causality classification of possible, and 26% were assigned a classification of unlikely, 13% of reports were assigned a conditional classification, meaning additional data was needed for proper assessment. Adverse event reporting statistics were provided in the February 2022 and August 2022 editions of the Medicines Information Bulletin.

The Clinton Health Access Initiative (CHAI) requested the support of MCAZ in conducting drug safety monitoring and reporting training at 20 CHAI Implementing sites for Tuberculosis Preventative Treatment (TPT), Paediatric Dolutegravir (pDTG) and Advanced HIV Disease (AHD) management. The 20 CHAI implementing sites trained in 2022 were Mbuma Mission Hospital, Lady Barring Hospital, Emakhandeni Polyclinic, Northern Suburbs Clinic, Mpilo Central Hospital, United Bulawayo Hospitals (UBH), Mandava Clinic, Mkoba Polyclinic, Al Davies Clinic, Mbizo 11 Clinic, Glenview Polyclinic, Budiriro Polyclinic, Rujeko Polyclinic, Parirenyatwa Hospital, Sally Mugabe Hospital, Chitungwiza Hospital, Epworth Polyclinic, Overspill Clinic, Dombotombo Clinic and Ruwa Rehabilitation Hospital. The main objective of the trainings was to capacitate healthcare workers on reporting and management of adverse drug reactions related to antiretroviral and anti-tuberculosis medicines. This would help to support strengthening of the national pharmacovigilance system by improving reporting of adverse events.

Pharmacovigilance and Clinical Trials Division

Vaccines Vigilance

The National Pharmacovigilance Centre, MCAZ, in partnership with Zimbabwe Expanded Program on Immunization (ZEPI) Ministry of Health and Child (MoHCC), are the main drivers of vaccine safety surveillance. In 2022, 28 Adverse Events Following Immunization (AEFIs) were received and in 64% of these reports, COVID -19 vaccines were the suspected medicines. These reports were all uploaded onto the MCAZ e-PV system and processed, and subsequently submitted to VigiBase. This was a significant decline from the 445 reports received in 2022 which could be attributed to a decline in the rate of COVID-19 vaccination. Feedback was provided for all the reports received and processed.

Pharmaceutical Industry Vigilance

In 2022, 2 circulars were published for the purposes of communicating pharmacovigilance requirements in Zimbabwe to all current and prospective applicants, manufacturers, and Market Authorisation Holders (MAHs) for all medicines to be marketed in Zimbabwe. Circular 3 of 2022 clarified the conditions for registration and subsequently expanded section 15 of the registration certificate as an annexure that is meant to capture more information on the conditions for registration, including mandatory reporting of ICSRs, the requirement for all marketing authorization holders to have a functional Pharmacovigilance system in place and a qualified person for pharmacovigilance (QPPV). Circular 13 of 2022 served as a notice to all applicants, manufacturers, and Market Authorisation Holders (MAHs) of medicines and vaccines registered and /or granted Emergency Use Authorisation (EUA) that the Authority required all MAHs to have a functional pharmacovigilance system in place in line with 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. As a result, an increase in the number of submitted QPPV notifications and GVP compliance increased.

The following meetings and trainings were done with Pharmaceutical industry representatives to provide training and feedback on updates related to Qualified Persons for Pharmacovigilance (QPPV) and Good Vigilance Practices (GVP) requirements:

Table 3: Trainings and feedback meetings held with Pharmaceutical Industry representatives in 2022

	Meeting title	Venue	Date
1	29th Human Liaison meeting with the Pharmaceutical industry (Presentation on QPPV and GVP inspections done)	Online	24 March 2022
2	Pharmacovigilance meeting with Pharmaceutical Industry on GVP inspections	Online	20 April 2022
3	Good Pharmacovigilance training – Pharmaceutical industry	Online	21 September 2022

A total of fourteen (14) signals and safety notifications were submitted by various applicants in 2022 and processed by MCAZ. This was a significant increase from the three (3) signals received in 2021. From these submissions, for twelve (12) reports the PVCT Committee agreed that there was no market action or additional risk minimization measures required at this time. The remaining two safety signals were for concerns around the use of sodium valproate by pregnant women and women of childbearing potential and a safety concern regarding decreased vitamin B12 deficiency in individuals receiving a higher dose of metformin or long treatment duration and in those with existing risk factors. The Committee recommended that a circular must be drafted and circulated communicating the safety measures for valproate and risks of congenital malformations and a warning on birth defects should be added for valproate in the future revision for EDLIZ. A letter was written to National Medicine and Therapeutics Policy Advisory Committee (NMTPAC) to include the warning in the next review for EDLIZ. The Committee recommended raising more awareness for the safety concern regarding decreased vitamin B12 levels in individuals receiving a higher dose of metformin or longer treatment duration and in those with existing risk factors

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, and 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. In 2022, the draft Zimbabwe Haemovigilance Guidelines and Transfusion reaction reporting forms were prepared and reviewed at a Hemovigilance task team meeting facilitated by the Paul-Ehrlich-Institut (PEI) as part of the BloodTrain program. The PEI - GHPP - BloodTrain team is supporting African partner countries in developing further capacities to improve access to safe blood and blood products

for patients. The Haemovigilance Task Team for Zimbabwe consists of haemovigilance experts from MCAZ, the National Blood Service Zimbabwe (NBSZ), and Paul Ehrlich Institute -Global Health Protection Program -BloodTrain team. The draft haemovigilance guideline and policy are currently under final review, following their circulation to stakeholders for comments. Trainings of haemovigilance focal persons from blood establishments and hospitals will be conducted once the Zimbabwe Haemovigilance guideline and policy are finalised.

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), in order to maintain a human and 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 for, 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 2022.

Table 4: Retention fees collected for the year 2022.

Income line	Expected Annual Target	Amount Received	Percentage of the Annual Target
Retention fees – Allopathic foreign medicines	US$1 072 063.50	US$998 405.50	93%
Retention fees – Allopathic local medicines	ZWL$12 508 987.50	ZWL$12 508 987.50	100%
*Retention fees – Complementary foreign medicines	US$37 269.75	US$34 006.50	91%
*Retention fees – Complementary local medicines	US$801.50	US$801.50	100%

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

As highlighted above 93% of the expected target was reached for retention fees of products which are manufactured externally. This might have be due to negative effects of COVID-19 pandemic experienced by the foreign applicants. However annually at least 5% products registration are voluntarily cancelled by the applicants by not paying retention fees and 90-95% of the target amount usually collected annually. The local applicants performed very well in payment of 2022 retention fees and the amount collected met the target. All the local the applicants paid their fees due in full amount. Retention fees collected for local complementary medicines was 91%.

Post-registration vigilance regulatory function:

Safety variations Periodic Safety Update Reports/ Periodic Benefit Risk Evaluation Reports (PSUR/PBRER), recategorizations, signals and promotional materials :

Post registration applications such as safety variations, re-categorizations 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 5: Post-registration submissions received by the PVCT Division in 2022

Category	Applications received	Applications processed	Timeline for processing (months)	Actual time taken(months)
Package insert updates	80	80	2	2
Additional Indications	1	1	2	2
Periodic Safety Update Reports/ Periodic Benefit Risk Evaluation Reports (PSUR/PBRER)	8	8	2	2
Re-categorizations	2	2	3	3
Promotional materials	32	32	2	2
Safety Signals	14	14	2	2
Totals	**88**	**88**		

The number of Periodic Safety Update Reports/ Periodic Benefit Risk Evaluation Reports received in 2022 was the same as that received in 2021. An increase in the number of package insert update applications, applications for changes in the category for distribution and promotional material applications received in 2022, with 80, 2 and 32 applications being received in contrast to 48, 1 and 24 applications received in 2021 respectively. In contrast, one (1) application for approval of an additional indication was received in 2022 compared to the 6 applications received in 2021.

Changes in Category of Distribution for Medicines based on ingredients

The Authority received two (2) applications for changes in the category of distribution in 2022. After review and consultation the following changes in category for distribution were approved by the Authority;

i. Loratadine 10mg tablets and 5mg/5ml syrup from Pharmacist Initiated Medicines (P.I.M.) to Pharmacy Medicine (P)

ii. Cetirizine 10mg tablets and 5mg/5ml syrup from Pharmacist Initiated Medicines (P.I.M.) to Pharmacy Medicine (P)

Projects

In 2022, the division continued with the implementation of the following projects:

The use of e-health to improve post-marketing surveillance of vaccines in Zimbabwe. A case study of Stimulated Telephone Assisted Rapid Safety Surveillance (STARSS) randomized trial assessing Adverse Events Following Immunization (AEFIs). Version 5.0 dated February 2021. (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 a mHealth new way to collect information about adverse events that sometimes occur after vaccination. This mHealth new way makes 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 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 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 4,500 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 results of the study will be published in due course.

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

The project is funded by the European and Developing Countries Clinical Trials Partnership (EDCTP). The aim of the SPaRCS project is to strengthen pharmacovigilance systems and clinical trials oversight of National Regulatory Authorities (NRAs) in Namibia, South Africa, Eswatini and Zimbabwe. The project uses a participatory action learning, and co-creation approach to develop personal and institutional capacities of the NRAs in the four countries. In March 2022, the first physical Project Steering Committee (PSC) meeting for the SPaRCS project was held in Cape Town, South Africa, and three representatives from the NRAs/PV centres of each of the 4 participating countries i.e. Zimbabwe, Namibia, South Africa and Eswatini attended the meeting. MCAZ also hosted an exchange visit and

workshop from 10 to 12 October 2022 that focused on the collaborative approach utilized by the MCAZ and MRCZ in clinical trials oversight. The visit involved a workshop on clinical trial oversight held in Victoria Falls as well as a joint GCP inspection with MCAZ, MRCZ and the trainees from Eswatini, South Africa and Namibia regulatory agencies.

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 of this, the MCAZ through the PVCT division designed an intensive course to build capacity and equip regulators in clinical trials and pharmacovigilance. In 2022, the division managed to conduct four (4) RCORE trainings highlighted in the table below:

Table 6: RCORE Trainings conducted in 2022

Country	Institution(s) Trained	Name of Course	Training Dates
Eswatini	Eswatini Human & Health Research Review Board (EHHRRB) and Ministry of Health Medicines Regulatory Unit (MRU)	Eswatini National Ethics Committee, and Ministry of Health Medicines Regulatory Unit (MRU) Team Clinical Trial Oversight and GCP Inspection training	3 to 6 May 2022
Eswatini, South Africa and Namibia	Ministry of Health - Eswatini, National Medicines Regulatory Council, Ministry of Health and Social Services - Namibia, National Department of Health - South Africa	EDCTP SPaRCS Clinical Trials workshop and GCP inspection training	10-12 October 2022
Mauritius	National Pharmacovigilance Unit - Ministry of Health and Wellness –	WHOGBT self-benchmarking virtual Training for the Vigilance function	21 October 2022, 10 November 2022
Botswana	Botswana Medicines Regulatory Authority (BOMRA)	-Training on Clinical Trials Protocol Assessment using AVAREF templates	26-28 July 2022

Publications

In order to disseminate medicine information, the PVCT division managed to publish two (2) editions of the Medicine Information Bulletin in 2022. The bulletins were distributed through various channels to all the relevant stakeholders and are electronic versions are available on the MCAZ website. The bulletins covered the following topics;

- COVID – 19 Vaccines Update
- Guideline for Pharmacovigilance of COVID-19 Vaccine- AEFI Safety Surveillance
- Good Pharmacovigilance Practices (GVP) – Pharmacovigilance Inspections
- Qualified Person for Pharmacovigilance (QPPV)
- Zimbabwe ADR Reporting in 2021 – Highlights
- Substandard and Falsified Medicines Alerts
- MCAZ Pharmacovigilance updates 2022: AEFI surveillance, ART & TB Programs
- Safety measures for sodium valproate and the risk of congenital malformation

The published bulletins are accessible via the following links:
Medicines Information Bulletin February 2022 edition: https://www.mcaz.co.zw/wp-content/uploads/2022/03/MCAZ-Medicines-Information-Bulletin-February-2022-Final-version-25-February-2022.pdf
Medicines Information Bulletin August 2022 edition: https://www.mcaz.co.zw/wp-content/uploads/2022/09/Medicines-Bulletin-August-2022.pdf

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 2022 in line with the training plan to develop their capacity. All of the trainings were conducted virtually.

Table 7: PVCT Staff trainings conducted in 2022

Program/Course	Date	Venue	Number of officers trained
Dossier assessment for clinical assessors within African regulatory agencies	08/2021 -3/2022	Online	4
Good Clinical Practice training	26/4/2022	Online	2
Introduction to Pharmacovigilance	27/4/2022	Online	4
Drug induced liver injury (DILI)	15/6/2023	Online	3
PV Management systems and terminologies	9/6/2023	Online	4
VigiLyze Introductory Course	4/7/2022	Online	1
Clinical trials protocol assessment using AVAREF templates	26-28/07/2022	Online	9
Essentials of Pharmacovigilance Communication	30/6/2022, 11/10/2022	Online	2
Collecting High Quality ADR reports	11/10/2022	Online	2
Introduction to Clinical Research	17/10/2022	Online	1
ICH Good Clinical Practice E6 (R2)	17/10/2022	Online	2
The Research Question	17/10/2022	Online	1
Introduction to Informed Consent	17/10/2022	Online	1
The Study Protocol: Part 1	17/10/2022	Online	1
Good Clinical Practice	17/10/2022	Online	2

Key/notable achievements

The MCAZ PVCT Division has conducted several regional vigilance and clinical trials regulation courses for other national regulatory agencies over the years and in collaboration with Medical Research Council of Zimbabwe (MRCZ), European Development Clinical Trials Partnership (EDCTP) participated in projects such as the SPaRCS project.

Since 2012 to date, the MCAZ in collaboration with the Ministry of Health and Child Care Public Health Programs (PHPs) embarked on a strategy of strengthening pharmacovigilance of through integration of PV into public and private health programs using Smart Safety Surveillance (3S) concept

initiatives. This included health care workers trainings in all provinces, and districts including consumer engagement through radio shows, advertisements, Med Safety promotions and online mobile safety reporting tools and PV projects. As a result, a total of 6 077 reports were received at by MCAZ from 1998 to 2022 of which 3595 (59.2%) were ADRs mostly related to antiretrovirals, 1033 (17.0%) were SAEs from clinical trials and pharmaceutical industry, 1110 (18.3%) from vaccines and 339 (5.5%) from COVID-19 vaccines.

The scope of vigilance has been further expanded and clarified through updates to the Pharmacovigilance Guidelines for Pharmaceutical Industry (MCAZ/PVCT/GL-02, Rev 1_February 2022) and publication of MCAZ circulars 3/2022 and 13 /2022.

Lessons learnt and Challenges

Lessons learnt

- There is a need to continue increasing automation of all the process e.g., for processing retentions fees this reduces processing timelines.
- Virtual meetings were effective particularly for those unable to join the meetings physically however it was noted that the quality of contributions can be compromised since people would be multitasking sometimes.
- The number of ICSRs submitted to MCAZ increases as more Pharmacovigilance trainings are conducted

Challenges

- The main challenge facing the pharmacovigilance system in Zimbabwe is under-reporting. The MCAZ in partnership with the Ministry of Health and Child Care (MoHCC) as well as donor partners regularly conduct awareness trainings to promote reporting of adverse events.
- Submission of incomplete reports, or reports with insufficient data is another challenge, and this is mitigated through regular trainings and stakeholder engagements.

Plans for the future

- Use of a new mobile AEFI surveillance and reporting systems known as VigiMobile and VigiFlow for AEFI for use by healthcare professionals. VigiMobile is an app 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 AEFI (from the district to the national level allowing

supervisors to review, monitor and process the data on the national database (VigiFlow). When integrated with VigiMobile the flexibility is tremendously enhanced permitting AEFI reporting from the field to the national database (VigiFlow) allowing supervisors to review, monitor and process the data on the national database.

The Zimbabwe "live" VigiFlow for vaccines safety AEFI report form for use by healthcare professionals is now available and can be accessed using the following link: https://vigiflow.who-umc.org

The Zimbabwe "live" VigiMobile for vaccines safety AEFI report form for use by healthcare proffesionals can be accessed using the following link: https://vaccine-primaryereporting.who-umc.org/zw_aefi The VigiMobile application can also be downloaded using the QR codes below:

OR

The National VigiFlow/ VigiMobile tools for AEFI reporting training was conducted from the 27th of February to the 1st of March 2023 and it was facilitated by the WHO with support from the MoHCC-EPI, CDC and the MCAZ. The provincial nursing officers (PNOs), PEPIOs and provincial health information officers (PHIOs) from the eleven provinces in Zimbabwe were in attendance.

- · Full automation of all the processes such as the retention fees, SAEs reporting systems etc.

Chemistry Laboratory

Introduction

The Medicines Control Authority 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 Zimbabwe public. The purpose of testing is to check quality attributes of medical products so that the Zimbabwean population is not exposed to falsified and sub-standard medical products. This is done in collaboration with the Ministry of Health and Child Care (MOHCC), World Health Organisation (WHO) and African Medicines Quality Forum (AMQF) and funding from development partners such as The Global Fund to Fight AIDS, Tuberculosis and Malaria, through United Nations Development Programme (UNDP). The Global Fund through UNDP has a long term agreement (LTA) with Chemistry laboratory 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 has the capacity to 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 Pharmacovigilence and Clinical Trials (PVCT) Division.

iv. Where pre-registration testing is necessary the laboratory performs chemical testing to establish quality of the medicines before they are allowed onto the Zimbabwean market.

The main objective being 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 lifesaving essential medicines, anti-retroviral, anti-TB and anti-malarial medicines.

Chemistry Laboratory

Laboratory Statistics

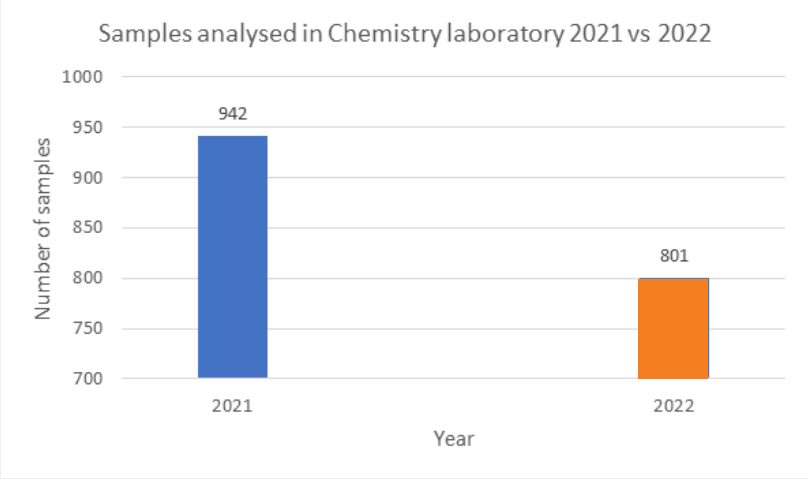


Figure 1: A comparison of samples analysed by the Chemistry Laboratory 2021 - 2022

During the year 2022, eight hundred and one samples (801) were analyzed. The samples analysed included medicines collected in the pharmaceutical distribution channel in Zimbabwe as part of post market surveillance. The samples also included post-market surveillance samples received by the laboratory from customers outside Zimbabwe in different African countries. It is important to follow up registered medicines in the distribution chain in order to combat the problem of counterfeits and substandard medicines. 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 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 2022 included anti-malarials (12%), anti-tuberculosis (25%), and anti-retrovirals (42%), other essential medicines (21%) as illustrated in Figure 2.

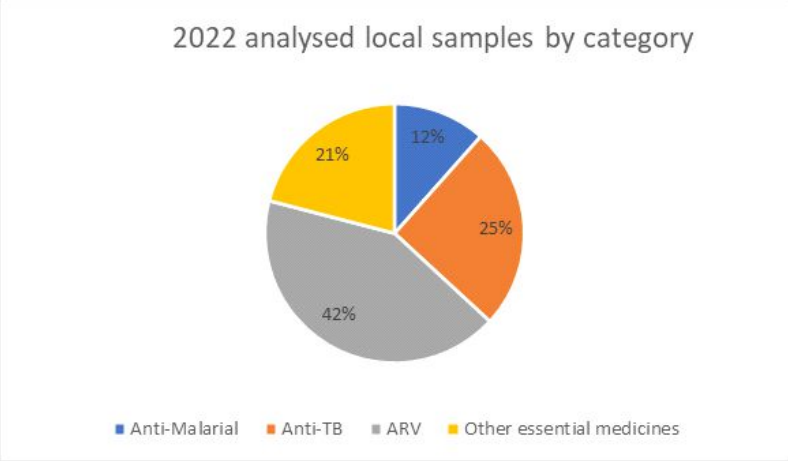


Figure 2: Distribution of analysed samples by classification

For the ARV samples analysed for local post-market surveillance in Zimbabwe, 73% were triple combination samples, 15% were dual combination, and were 12% single formulation samples as shown in figure 3.

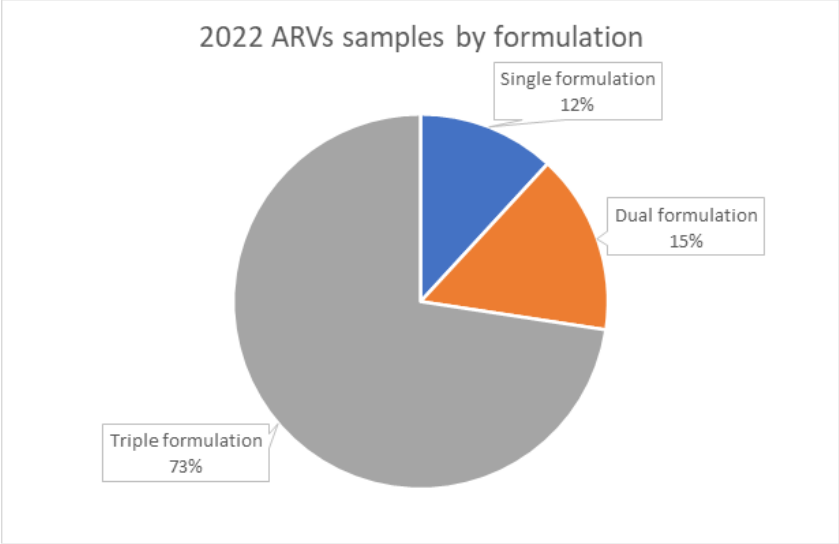


Figure 3: Distribution of analysed ARV samples by formulation

For anti-TB samples, quadruple formulation were the bulk of samples (38%) followed by single formulation samples (35%). Dual formulation samples were 26% and triple formulation samples were 1% as illustrated in figure 4. The triple formulation samples were scarce at health centres and sampling sites.

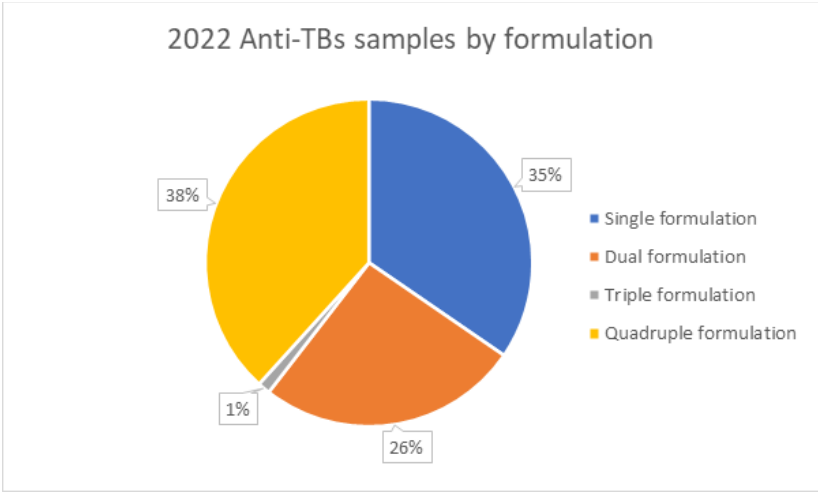


Figure 4: Distribution of analysed anti-TB samples by formulation

External customers

In 2022, the Chemistry Laboratory analysed samples for customers outside Zimbabwe. The samples included those brought under Global Fund/UNDP LTA from countries such as Burundi, Chad, Djibouti, Guinea Bissau, South Sudan and Sudan. In addition, the laboratory tested samples received from Cordaid Democratic Republic of Congo (DRC), Madagascar and Zambia. The volume of external samples received from each customer is shown in Figure 5.

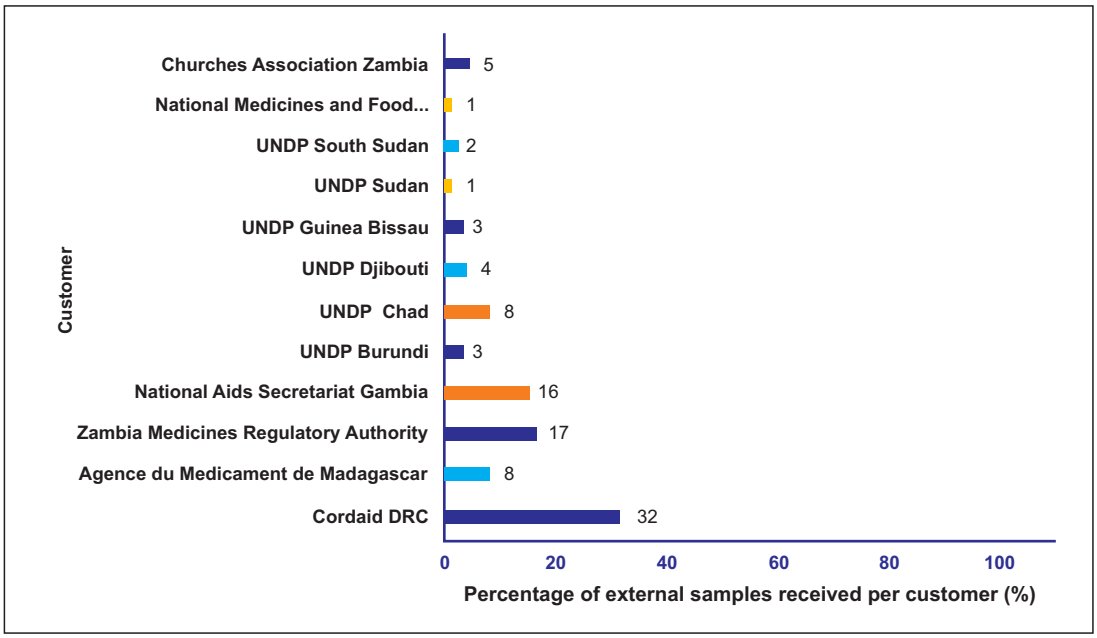


Figure 5: Samples analysed for customers outside Zimbabwe

Chemistry Laboratory

Inter-laboratory proficiency testing

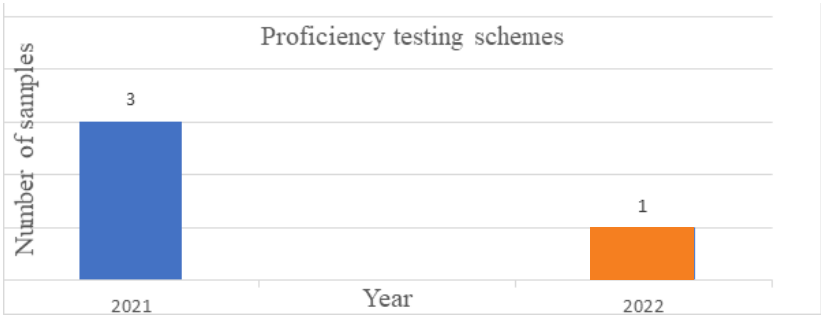


Figure 6: Samples analysed in proficiency testing schemes

The Chemistry laboratory in 2022 participated in one (1) inter-laboratory proficiency testing scheme coordinated by USP Ghana.

The technique assessed was Thin Layer Chromatography (TLC) for related substances of anti-malarial tablets.

Capacity development issues undertaken.

Drug and substance abuse has become a major concern to the population of Zimbabwe. This issue has affected both youths and adults across the nation. In an effort to find solutions to fight this challenge, a representative of MCAZ Chemistry laboratory attended a multi-stakeholders meeting on influx of illicit drugs and harmful liquids at Zimbabwe Republic Police (ZRP) Morris Depot Sports Club on the 30th March 2022. One of the resolutions of this meeting was for MCAZ to partner with ZRP Forensic Science Directorate in knowledge sharing and training of Forensic Science Officers on drug analysis.

Consequently, ZRP Forensic Scientists were trained on High Performance Liquid Chromatography (HPLC) analysis in Chemistry Laboratory from 30th May to 3rd June 2022. The training focused on theoretical and practical aspects of HPLC technique when applied to forensic analysis of drugs.

Key/notable achievements

In 2022, the Chemistry laboratory scored the following achievements:-

- Improved performance in terms of overall sample testing turnaround times.
- Retained SADCAS accreditation for the HPLC and UV-Vis techniques
- Maintained WHO Prequalification status
- Retained existing external customers and partnered with new ones. Improved customer satisfaction should continue to enhance revenue streams for the organisation.

Chemistry Laboratory

Challenges and lessons learnt

The Chemistry laboratory witnessed an increase in number of samples received for testing from customers outside Zimbabwe in 2022. However, there were challenges faced during customs clearance of some of the samples received from the external customers. Customs duties were required for the samples that were meant for destructive testing. Constant communication with our external customers and Zimbabwe customs officials turned out be the key that resolved the challenge. In addition, customers were encouraged to ensure that all documentation that accompanied the samples was filled in correctly and the purpose of testing clearly highlighted on the sample packages.

Plans for the future.

Cultivation of cannabis for medicinal use was legalised by the Government of Zimbabwe in 2018. The Chemistry Division intends to expand the scope of testing to include cannabis and complementary medicines by setting up a dedicated cannabis laboratory with state of the art equipment.

The laboratory is to be equipped with instrumentation including High Performance Liquid Chromatography (HPLC), Liquid Chromatography Mass Spectrometry (LCMS), Gas Chromatography Mass Spectrometry (GCMS), Inductively Coupled Plasma (ICP) and other instruments necessary for the analysis of cannabis, cannabis formulated products and complementary medicines.

MICROBIOLOGY LABORATORY

Introduction

The Microbiology Laboratory conducts microbiological testing of pharmaceutical preparations and allied substances. The samples received by the laboratory for testing are as indicated below:

- Pre-distribution analysis of medicines to ensure that good quality and safe products are circulated in the medicine's distribution chain.
- Post Market Surveillance.
- Adverse event monitoring in collaboration with the PVCT Division.
- Where pre-registration testing is necessary, the laboratory performs microbiological analysis to establish the quality of the medicines before they are allowed onto the Zimbabwe market.

Sample Statistics

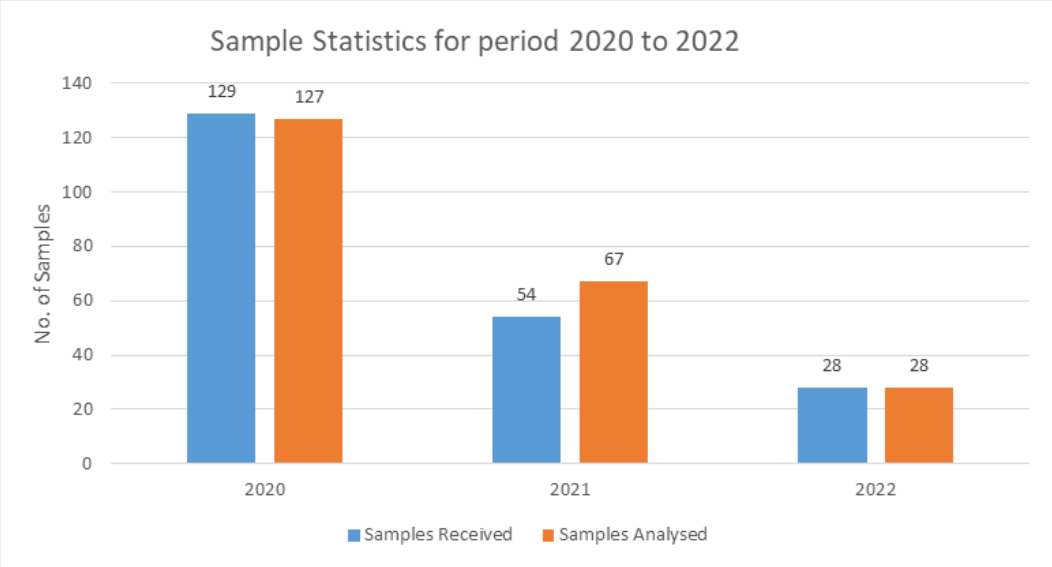


Figure 1: Trend Analysis of Samples received and tested by the Microbiology Laboratory (2020 to 2022)

- During the period under review (2022), the laboratory received and tested twenty-eight (28) samples.
- There is a general decline in the number of samples received by the laboratory for testing from the year 2020 to 2022.

Achievements

- The laboratory resumed participation in Proficiency Testing Schemes. The laboratory participated and performed very well in a proficiency testing scheme coordinated by LGC Pharmassure PT scheme. There were no outlier results in the year 2022.

MICROBIOLOGY LABORATORY

- Most samples received were tested within set turnaround times (85.7%), hence positively impacting on effective regulatory processes.

Plans for the future

Attainment of WHO Prequalification Status for the laboratory. This will enhance the reliability of test results generated by the laboratory, hence international recognition for the laboratory.

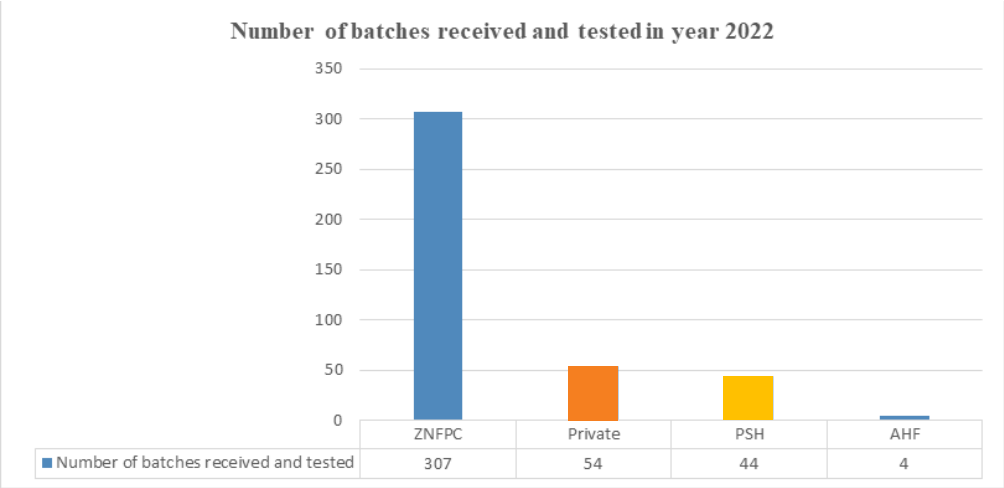
MEDICAL DEVICES LABORATORY

Introduction

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

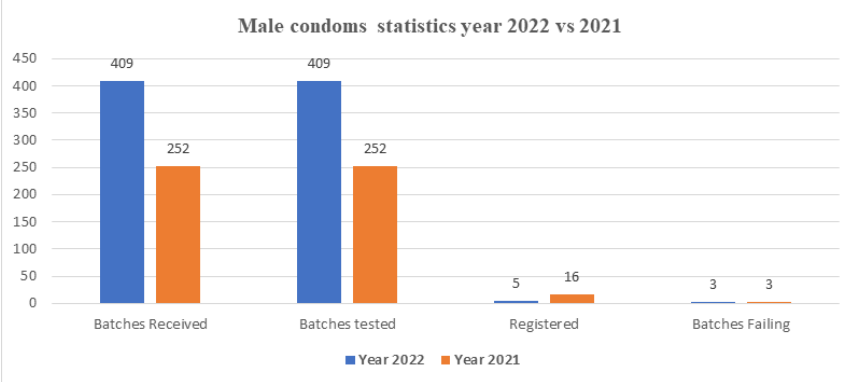
Activities/Major Highlights: 2022

Condoms



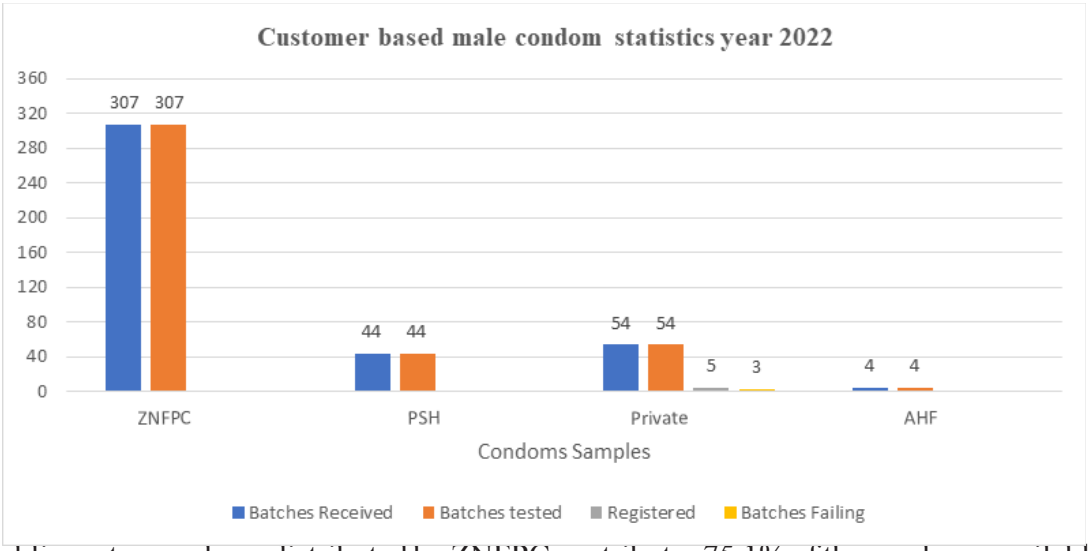
Snapshot of batches received and tested in 2022 according to source.

- The laboratory received and tested four hundred and nine (409) condom batches for testing in year 2022.
- Three (3) batches of condoms failed quality conformity assessment tests in the year 2022.
- SADCAS conducted a surveillance audit in year 2022, and the laboratory maintained its ISO 17025 accreditation status.
- The laboratory continues to participate in annual proficiency testing schemes coordinated by the FHI360 (USA) and Enersol (Australia).



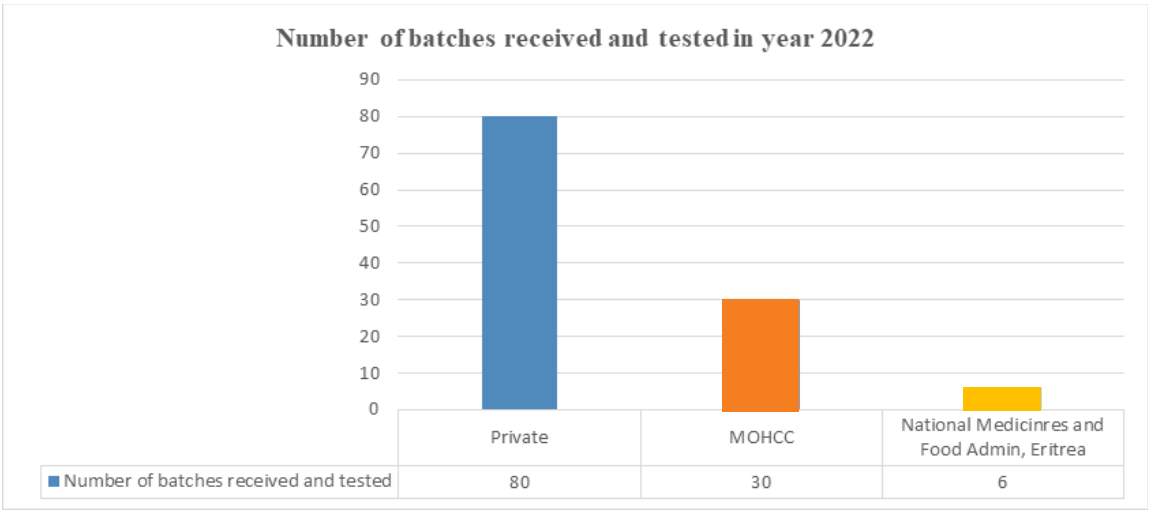
MEDICAL DEVICES LABORATORY

- There was a 62.3% increase in the number of samples received from year 2021 to 2022.
- There was a significant decrease in new condom registered in 2022 compared to 2021.



- Public sector condoms distributed by ZNFPC contributes 75.1% of the condoms available on the Zimbabwean market, followed by the private sector, which distributed 13.2% and lastly 10.8% for PSH.
- The three failed condom batches in year 2022 were from the private sector.

Gloves

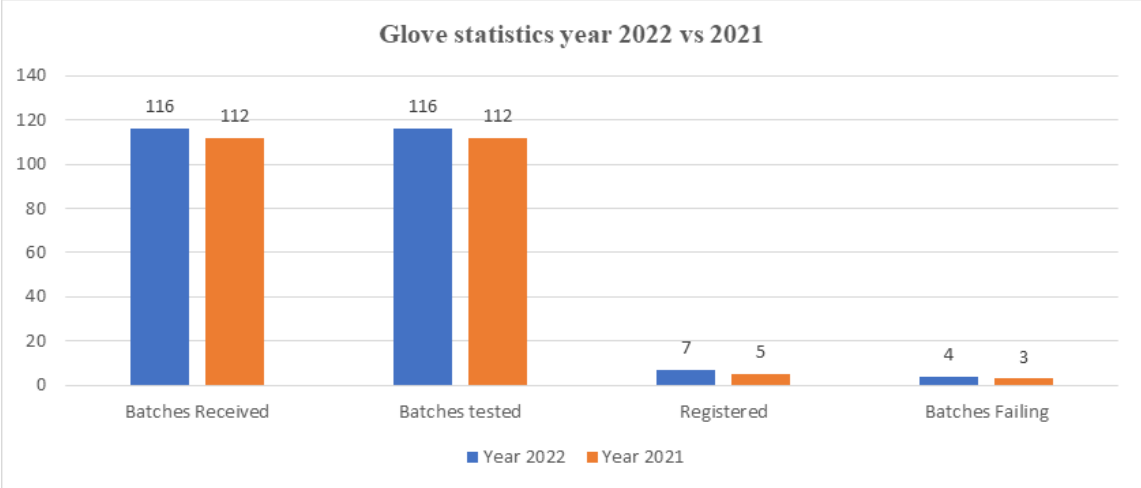


Snapshot of batches received and tested in 2022according to source.

- The laboratory received and tested one hundred and sixteen (116) batches of gloves in year 2022.
- The private sector contributed more than 60% of the glove batches, and the MOHCC contributed 26% of glove batches received and tested in year 2022.

MEDICAL DEVICES LABORATORY

- The laboratory continues to consistently and satisfactorily perform in annual Glove testing proficiency testing schemes coordinated by Enersol of Australia.



- There was a 3.6% increase in the number of glove batches received from year 2021 to 2022.
- The laboratory received seven (7) new glove registration applications for the period.
- Four (4) batches of gloves failed quality conformity assessment tests for the period.

Factory Audits

The following factories were inspected in year 2022 for compliance to the requirements of ISO 13485:2016 Medical Devices-Quality management systems (Requirements for Regulatory Purposes).

- P.T. Latexindo Toba Perkasa Pvt. Ltd, Indonesia (Medical Gloves)
- P.T. Arista Latindo, Jl. K. H. Moh. Mansyur No. 128 Jakarta 11210, Indonesia (Medical Gloves
- Maxter Glove Manufacturing, Malaysia (Medical Gloves)
- Qube Medical Products, Malaysia (Medical Gloves)
- Thai Nippon, Thailand (Public sector condoms manufacturer)
- SSL, Thailand (Private sector condom manufacturer)

The premises complied with the current standard for ISO 13485:2016, Good Manufacturing Practices and Zimbabwean regulatory requirements. 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 2022 work plan. Most samples received were tested within set turnaround times, hence positively impacting on effective regulatory processes. The lab performed very well in all the Proficiency Testing schemes for condoms

and gloves testing. There were no outlier results in year 2022. The laboratory coordinated the first regional condom proficiency testing scheme in partnership with UNFPA. The following countries participated in the scheme: Ethiopia, Zambia, Tanzania, Kenya, Uganda and Rwanda. Individual laboratory reports and the General report for the PT scheme were compiled and submitted to all participating laboratories.

Quality Unit

Introduction

To pursue a more focused, efficient, and appropriate work ethic, the Quality Unit in 2022 has continued to comply with Quality Management Systems (QMS) as evidenced by maintenance and retainment of key QMS accreditations and certifications, earmarked towards the Authority's effective execution of its Strategic Plan. The year commenced on an affirmative note, setting out Authority objectives and communication thereof, to employees. The cascade coupled the revised mission, vision, and values of MCAZ. The goals were in alignment with the Authority's Strategic Plan and World Health Organisation Global Benchmarking Tool (WHO GBT) requirements. To this effect, the Quality Unit managed to make follow-ups to relevant Units and Divisions towards rectification of raised Implementation Development Plans (IDPs), in partial fulfilment of the Authority's overall goal to attain WHO GBT Maturity Level three (ML3). Trainings were conducted successfully throughout the year to equip and accord officers with prerequisite principles that complements their inherent skills. The Unit continues to uphold good relations with other countries in the region, the Unit participated in bid preparations to host African Medicines Agency (AMA) and hosted Zambia Medicines Regulatory Authority (ZAMRA) towards their Internal Audit (Knowledge Sharing) with the Authority's Chemistry and Medical Devices Laboratories. These interactions were in prospect to subcontract MCAZ.

Activities

1. Internal Auditing and Effectiveness checks of QMS standards (ISO/IEC 17025:2017 ISO/IEC 9001:2015, ISO/IEC 17020:2012, WHO GBT and WHO Prequalification.
2. A total of 1788 samples were received in 2022 which was a 5% increase compared to 1712 samples received in 2021. There were 1338 test reports released which was a 5% increase compared to 1280 results released in 2021.
3. Monitoring of Key Processes Timelines for all Units and Divisions towards organizational performance measurement.
4. Consolidation, Monitoring, Analysis, Evaluation, and Implementation of the MCAZ Strategic Plan.

Focus on notable changes and developments. (statistics)

1. The Samples Repository Office was refurbished following the bid preparations to host AMA.

Quality Unit

Capacity development issues undertaken.

Capacity Development	Officers Developed
Requirements and Internal Auditing ISO/IEC 17020:2012 officers	Two (2)
Roll-Out of Revised Authority Objectives, Vision, mission, and Core Values	All Units/Divisions
Requirements and Internal Auditing ISO/IEC 9001:2015	Three (3)
MASCA and PECOGA	Nine (9)
Root Cause Analysis	Four (4)
Development and Implementation of ISO/IEC 17025:2017	Three (3)
Requirements and Internal Auditing ISO/IEC 17025:2017	Five (5)
Data Integrity and Computer Systems Validation	Two (2)
USP Foundations on GMP (10 Modules)	Seven (7)

Key/notable achievements

1. Maintenance of the SADCAS Accreditation in ISO/IEC 17025:2017 and ISO/IEC 17020:2012
2. Retaining of Standards Association of Zimbabwe (SAZ) ISO 9001:2015 Certification
3. Maintenance of the Chemistry Laboratory WHO Prequalification

Lessons learnt and Challenges.

We continuously learn that internal audits are a sampling phenomenon towards systems improvement, hence should be conducted more often to positively impact on the organisational performance. By taking heed of Covid-19 regulations, 2022 was a less impeded year towards more contact time amongst officers, however, we continue to utilise virtual platforms necessitated by the pandemic. Document Control processes continue to be paper based; it is a major challenge towards adherence to set timelines.

Plans for the future.

The future prospect for the 2023 is the continuous contribution by Quality Unit towards achieving ML3 in the WHO GBT Assessments and attainment of WHO PQ for the Microbiology Laboratory. These two achievements will be advantageous in achieving recognition, more revenue and above all to necessitate MCAZ to be enacted as a WHO Listed Authority. We are hopeful that Office 365 will offer solutions to our paper-based challenges posed in the Document Control Processes.

LEGAL UNIT

Introduction

The Legal and Corporate Affairs Unit contributes towards the mandate and vision of the MCAZ through the following:

a. Legal risk assessment and management
b. Reviewing and developing of legislation
c. Drafting and reviewing of contracts
d. Rendering legal advice to the Director-General, all Divisions, Units and Committees of the Authority
e. Interpretation of legislation
f. Coordination of cases for litigation with MCAZ external legal counsel
g. Management of the Legal and Corporate Affairs Unit internal business processes
h. Monitoring compliance of the Authority to Corporate Governance issues
i. Providing secretariat services to the Legal, Hearing and Audit Committees and the Legal Drafting Sub-Committee

It is the above activities that the Unit was involved in during the year 2022.

Achievements by the Legal and Corporate Affairs Unit

In 2022, the Legal and Corporate Affairs Unit made tremendous strides in fulfilling its mandate. Some of the notable achievements include the submission of Draft Regulations for approval to the Minister of Health and Child Care. The following Regulations were submitted for approval; the Import and Export of Medical Devices Regulations, Blood and Blood Components Regulations, and the amendment to the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2018, Statutory Instrument 62 of 2018. The Unit came up with proposed amendments to the Medicines and Allied Substances Control Act (Chapter 15:03) to align it to the African Union Model Law on Medical Products Regulations and to incorporate the recommendations that were made during the initial WHO GBT assessment. The proposed amendments were then reviewed by Management, the Legal Drafting Sub- Committee and the Legal Committee before being submitted to the Minister of Health and Child Care for approval. The Unit continued to participate in the WHO GBT assessment and assisted in responding to GBT requirements. During the year, the Unit conducted consultative stakeholders' meetings for the draft Personal Protective Equipment Regulations, Hand Sanitisers Regulations, and the Active Pharmaceutical Ingredient Regulations. The Unit further conducted the validation meeting and the final consultative stakeholders meeting for the Medicated Feed Regulations. The Unit also drafted the Local Production and Distribution of Medical Devices Regulations.

LEGAL UNIT

Hearings

In 2022, fifteen (15) hearings were conducted. Of the hearings conducted, five (5) person's licences were cancelled, one (1) premises licence was cancelled, six (6) wholesale dealers permits were revoked and three (3) final warnings were issued.

The most prevalent offence was the failure by the six (6) wholesalers to ensure that Histalix (codeine-containing formulation) procured from CAPS Pharmaceuticals was properly accounted for, leading to the revocation of their permits by the Hearing Committee.

The Hearing Committee was concerned with the facilitative role played by CAPS Pharmaceuticals in the cases relating to Histalix syrup and recommended the Authority to review its processes to come up with new methods which would ensure efficient monitoring of wholesale dealers. Consequently, purchasers now have to get authorisation from the Authority to purchase Histalix syrup and they also need to submit returns to the Authority where they account for the Histalix purchased.

Lessons learnt and challenges

Valuable lessons were picked up during the course of the year. It was noted that there was need for the Authority to actively engage the Ministry of Health and Child Care on all the draft legislation which awaits approval so as to expedite the approval of the legislation. It was further noted that it was crucial for the Authority to engage the Ministry of Health and Child Care during consultative stakeholders' meetings for all draft legislation. The Authority therefore intends to hold meetings with the parent Ministry in 2023 to take them through all the draft legislation where consultative stakeholders meetings were conducted.

Plans for the future.

The Unit plans to increase engagement with the parent Ministry on all steps in the drafting of legislation until the proposed legislation is submitted for approval. In 2021, the Unit assessed the Authority's degree of compliance to relevant legislation and compiled a compliance report. In 2023, the Unit intends to continue assessing compliance on all issues whilst emphasizing on corporate governance issues.

Human Resources

Focus on notable changes and developments. (statistics)

The year 2022 witnessed the implementation of a new 5-year strategic plan with more emphasis on service delivery, improved and effective talent management, good corporate governance and efficient use of resources. There was a marked increase in terms of the employee engagement index from the previous 26% to 49% following an outsourced external survey, although this was against a background of perennial loss of skills within the organization.

Capacity development issues undertaken.

The Authority continued with its investment in the learning and development of its human capital and the measuring of its human resource effectiveness in order to track the achievement of its strategic objectives. There were 83 key training and development programmes besides other necessary in-house programmes undertaken in the year compared to 73 programmes in the previous year. This initiative contributed to improved productivity, efficiency as well as job satisfaction.

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. Continued fostering and refinement of a high-performance culture with emphasis on performance contracts to manage and measure success, failure and improvement.
3. Upward review of employee remuneration including non-monetary incentives such as personal loans, motor vehicle loans, etc.

Lessons learnt and Challenges

The Authority's remuneration structure required to be benchmarked against regional medicines regulators, so that the issue of perceived low remuneration, loss of skills and low employee engagement were minimized. From a regional salary and benefits survey conducted, it revealed that overall, the Authority's total cost of employment package was below the average market by 20%. Therefore, it would be desirable to peg employee remuneration to at least 50th percentile of the average market, where sustainable, so that, the Authority would neither be paying below nor above the market average. The challenges faced were basically the same as before and these include narrow revenue streams, regulated fees, currency reforms, skills flight, etc.

Human Resources

Plans for the future.

Going forward, the Authority envisages to be 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, comparable remuneration structures among others.

INFORMATION AND COMMUNICATION TECHNOLOGY

The ICT Unit drives the Authority' automation of key business process strategy by providing a combination of home-grown solutions and international and regional collaboration solutions. The unit is driving the strategic goal to fully automate by 2026.

Key/notable achievements

The Unit have managed to implement Microsoft 365 which has a lot of benefits such as:

1. Cloud based email exchange.
2. Office applications (Excel, Word, PowerPoint etc),
3. SharePoint,
4. Project Planner for Task tracking,
5. Teams which will replace ZOOM and Webex
6. Forms which are used for Surveys.

The Unit developed and implemented a QR Code authenticator which validates issued Licenses, Certificate, Permits and Authorisation Letters.

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

7. Import and Export of registered medicines.
8. Import and Export of Narcotics
9. Import and Export of unregistered Medicines (Section 75 Authorisation)
10. 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 us internet and hardware (laptops) needs to be adequate to be able to provide online support services and support business applications.

Plans for the future

- To implement LIMS as a key enabler for streamlining laboratory processes including data integrity, tracking of samples up-to EOA reports.
- To implement an online portal for processing applications for Issuing of new premises and person.

- To implement a payment portal and CRM to allow users to make payments of their application online.
- To implement an online portal for both Local inspections and GMP Inspections.
- Full automation of retention fees processing system.
- To implement a mobile application for Drug lookup.