MCAZ

Medicines Control Authority of Zimbabwe

2021 Annual Report

Medicines Control Authority of Zimbabwe

Protecting your right to quality medicines and medical devices

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Abbreviations

ADR	Adverse Drug Reaction
AEFI	Adverse Event Following Immunisation
AHF	Aids Healthcare Foundation
ARVs	Antiretrovirals
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
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
PECOGO	Public Entities Corporate Governance Act
PEI	Paul Ehrlich Institute
PFMA	Public Finance Management Act
PQ	Prequalification
PSI-Zim	Population Services International- Zimbabwe
PVCT	Pharmacovigilance and Clinical Trials
QMS	Quality Management Systems
RCORE	Regional Centre of Regulatory Excellence
SBS	Small Business Support
SADC	Southern African Development Community
SADCAS	Southern African Development Community Accreditation Service
SAE	Serious Adverse Event
SAHPRA	South African Health Products Regulatory Authority
STARSS	Stimulated Telephone Assisted Rapid Safety Surveillance
TB	Tuberculosis
TSR	Targeted Spontaneous Reporting
TWG	Technical Working Group
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
VICH	Veterinary International Conference on Harmonization
VSN	Vaccine Safety Net
WHO	World Health Organization
ZAMRA	Zambia Medicines Regulatory Authority
ZIMRA	Zimbabwe Revenue Authority
ZNFPC	Zimbabwe National Family Planning Council

Chairman's Foreword

The year 2021 was the last year of the Medicines Control Authority of Zimbabwe's three-year strategic plan (2019-2021) and it is my pleasure to present the 2021 Annual Report. Overall, the Authority managed to achieve its goals and execute its mandate despite the challenging operating environment.

Governance

The Authority had eleven members at the beginning of 2021.During the course of the year, a number of long-serving committee members retired from some board committees. I wish to express my gratitude to the outgoing members for their contributions to MCAZ's governance as well as the execution of its mandate. In June 2021 the board also welcomed Air Commodore (Rtd) P. Zimondi as a member of the Authority. Five members of the Authority had their terms of office renewed for another term to 2025. Following Ms. G N Mahlangu's retirement as MCAZ Director-General on 31st December 2020, Mr. R T Rukwata was appointed Acting Director General. On behalf of the board, I thank Mr. Rukwata for his industrious leadership at the helm of the organization in the interim.

Meetings and Quorum

The year 2021 was also characterised by the COVID-19 pandemic which resulted in the Authority's meetings as well as Committees' meetings being held virtually or in a hybrid manner. This allowed the Authority to conduct its business successfully. The Authority also managed to hold the Annual General Meeting (AGM) in October 2021 for the year ending December 2020.

I would like to commend the commitment shown by our board and committee members in attending all our meetings as all meetings were quorate. The summary of attendance for board and committee members is included for stakeholders' perusal. Our board and committee members were committed to attending all scheduled meetings and providing their relevant expertise in the discharge of the Authority's mandate of protecting public and animal health.

Strategy

The board continued its oversight role over the implementation of the organisation's strategic plans through the Finance Committee. The Authority also came up with a new five-year strategic plan for the period 2022 to 2026. The new five year strategic plans take cognisance of and support the national agenda as set in the National Development Strategy 1 (NDS1) and in line with the Ministry of Health and Child Care (MoHCC) vision "to provide, administer, coordinate, promote and advocate for the provision of equitable, appropriate, accessible, affordable, and acceptable quality health services and care to Zimbabweans while maximising the use of locally available resources in line with the Primary Health Care approach". The successful implementation of the COVID 19 vaccination strategy by the Government of Zimbabwe saw the relaxation of COVID-19 restrictions allowing the Authority to implement its annual plans. Further details will be covered in the Acting Director-General's statement as well as the departmental updates in this report.

Future

The Authority challenges Management and Staff to stay focused on improving service delivery for the attainment of the Authority's mission and vision as articulated in the strategic plan. We trust that under the "new normal" brought about by the COVID-19 pandemic, the Authority will continue to provide its customers and stakeholders with excellent services through the automation of our processes as well as other customer-centric initiatives.

Dr M. Chiware
Authority Chairperson

Acting Director General's Statement on 2021 Performance

I am honoured to present a synopsis of the performance of MCAZ for the year 2021. This report reflects on our operations in 2021 and it focuses on providing deeper insights into the operations of each unit and division of the Authority. The year 2021 marked the end of our three-year strategic plan which ran from 2019-2021 as well as the 24th year of the operations of MCAZ as the National Medicines Regulatory Authority for the country of Zimbabwe. We continued to grapple with the restrictions imposed by the COVID-19 pandemic, which called for creativity and adaptability in the way we execute the Authority's mandate. I am glad to report that the Authority remained steadfast in its endeavour to fulfil its mandate as stipulated in the governing statutes.

In 2021, global efforts to tackle the COVID-19 pandemic continued, with the Authority issuing emergency use authorizations (EUAs) for COVID-19 vaccines and providing scientific recommendations on Covid 19 therapeutics that the country needed to protect the health of its citizens.

On the backdrop of Government of Zimbabwe efforts to curb the impact of the pandemic, we managed to implement most of our annual plans and anchored our activities towards our vision and attainment of our goals. As defined by our strategic goal, "to be a WHO listed Authority with a customer satisfaction of 80% by 31 Dec 2021," the Authority had an initial WHO Global Benchmarking Tool (GBT) assessment done in August 2021 and is currently working on addressing the identified shortcomings. We also developed a five-year strategic plan at the end of 2021 which will provide strategic focus for the Authority from 2022-2026. The new strategic plan incorporates themes in the National Development Strategy 1 (NDS1) which was launched by the Government of Zimbabwe in November 2020.

The Ministry of Health and Child Care (MoHCC) in its strategic plan (2021-2023), also emphasises the need for improved access to essential medicines and commodities, the harmonisation of quantification, procurement, warehousing, and distribution through the introduction of electronic Logistic Management Information System (e-LMIS) which will include critical private sector functions and the promotion of local manufacturing of medicines and medical products. MCAZ has paid particular attention to its responsibilities in support of the above, with the establishment of a Small Business Support (SBS) Unit in 2021. The purpose of the SBS unit is to provide local manufacturing support and facilitative assistance, under the key programmes of bio-medical engineering, bio-medical sciences, pharmaceutical and bio-pharmaceutical production. This is in line with the Ministry's thrust towards increased local production of medicines to reduce the country's reliance on imported medical products.

The Authority was adaptive to the COVID-19 induced work models. We introduced flexible and remote working models which brought their own challenges since our systems were not fully geared for the challenges that these models would introduce. We however prevailed as our stakeholders will attest to the continuous delivery of services during the peak of the pandemic.

The pandemic also affected some of our revenue lines such as new applications received, as well as local and external physical GMP inspections due to suppressed business activity during the pandemic. However, in 2021 a slight increase was recorded. Despite the pandemic the Authority managed to live within its means and aspires to continue on this path into the foreseeable future.

Business Process

Meetings: The relaxation of COVID-19 regulations following the roll-out of the vaccination campaign by the government saw the reintroduction of face-to-face meetings. However, most of our board and committee meetings used the hybrid model, whilst virtual meetings also continued. Most meetings were held successful, allowing the Authority to execute its statutory mandate effectively in spite of the challenges.

Submissions: The Evaluations and Registration unit surpassed its target for the year with new registrations for human medicines increasing by 37% while veterinary medicines registrations increased by 23%. A notable increase was also recorded in complementary medicines with fifty-five (55) applications for complementary medicines approved bringing the total of approved products to two hundred and ninety-five (295). This represents a 30.95% increase compared to the previous year.

Acting Director General's Statement on 2021 Performance

Remote working: In line with the regulations from MoHCC, our staff continued to work in rotation with a proportion of the total staff complement occupying office space on a rotational basis whilst the rest worked remotely. Flexibility and remote work ensured that the Authority's work output was not negatively affected by the lockdowns. With the relaxation of the lockdown measures the Authority maintained the remote work model where appropriate or desirable. The work diaries introduced in 2020 proved to be an effective monitoring tool on the productivity of the staff working remotely.

Customers and Stakeholders

Our customers were encouraged to access our services online where possible. Leading to the pandemic, the Authority had been on a drive to automate its service delivery, this helped a great deal when the pandemic struck as we were able to provide services to our customers via these online systems. There were some teething problems with some of these systems but our focus on continuous improvement has ensured that these systems got better with time based on customer feedback and in-house skills development within our ICT team. All consultative stakeholder and liaison meetings were shifted from face-to-face to virtual platforms. Whilst Covid imposed constraints on our ability to convene physical meetings that were usually attended by local agents of foreign principals, the virtual online meeting platforms opened the opportunity of limitless global reach where foreign principals and stakeholders abroad were able to join some of our meetings remotely.

We wish to thank the Global Fund and UNDP for supporting the MCAZ to refurbish its microbiology laboratory pursuant to our commitment to provide quality-assured microbiology testing of medicines used in Zimbabwe and other countries to whom we provide testing services.

Corporate Social Responsibility

As part of our corporate social responsibility programmes (CSR), the Authority continued to identify and support disadvantaged university students pursuing studies in pharmacy at the University of Zimbabwe and the Harare Institute of Technology. In 2021, three (3) students Part IV students sponsored by the Authority successfully completed their pharmacy degree programmes.

The future

The microbiology laboratory is yet to be pre-qualified by the World Health Organisation, we are working towards attainment of this goal. We shall also be working towards the establishment of a laboratory for the analysis of cannabis as this is an area of growing interest which requires the Authority's expertise.

I would like to thank the Authority members, Management team, all members of Staff, and all stakeholders for making 2021 yet another success. We look forward to 2022, the year that the Authority will be celebrating its 25th Anniversary.

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Mr. Richard T Rukwata

Acting Director General

Overview of the Authority

MISSION
To protect public and animal health by ensuring that accessible medicines, allied substances, and medical devices are safe, effective and of good quality.

VISION
To be an effective medicines regulator in Zimbabwe and a leading regulatory authority in the world.

CORE VALUES
- Customer Focus
- Integrity
- Continuous Improvement
- Accountability

2019 - 2021 STRATEGIC GOAL
To be a WHO listed authority with a customer satisfaction of 80% by 31 Dec 2021.

Governance and Risk Report

Governance Overview

The Board considers good corporate governance as a critical component to the viability and performance of the entity and provides assurance to the Authority's stakeholders that strengthening the existing framework for governance and compliance remains high on its agenda. MCAZ stakeholders include the Government of Zimbabwe, Ministry of Health and Child Care (MoHCC), other government institutions, the pharmaceutical industry, customers, suppliers and the general public. The Authority adheres to the principles of corporate governance derived from the following;

- Medicines and Allied Substances Control Act (MASCA) *Chapter (15.03)*
- Public Finance Management Act (PFMA) *Chapter (22.19)*
- Public Entities Corporate Governance Act (PECOGA) *Chapter (10.31)*
- King Code on Corporate Governance 2009 (King III)
- Corporate Governance Framework (CGF) for State Enterprises and Parastatals
- International Financial Reporting Standards (IFRS)
- MCAZ Board Charter

During 2021, the Corporate Governance Unit (CGU) in the Office of the President and Cabinet produced a Compliance Assessment Survey Report showing that MCAZ had overall score of 59% for a compliance assessment survey conducted in 2020. As a result, MCAZ was categorized as one of the entities in the medium compliance range, meaning that it is compliant with at least 50% of the provisions of the PECOGA but there were some areas noted that need to be improved.

The Board and its Function

The Board provides oversight and strategic direction of all Authority operations in line with guidelines set in the Board Charter. Its other roles include monitoring delivery of the strategy within the risk and control framework set by the Board, satisfying itself on the integrity of the financial information and the effectiveness of financial controls and the risk management systems.

The Board has eleven members, with all members including the Chairman being Non-Executive Directors. During 2021, long-serving Board and Committee members that had exceeded two terms (i.e. 8 years) and some three terms (i.e. 12 years) were retired from Board Committees and new members were subsequently appointed. The Board and Committees were able to conduct all scheduled quarterly meetings in spite of Covid, with some of the Committee meetings being held virtually or in a hybrid manner.

Sadly, we lost two serving members of the Authority. In January 2021 we received news of the passing on of Dr J. Chidora who was a Board member and also Chairperson of the Human Resources Committee. Dr J. Chidora joined the Authority in March 2017 and was serving her second term in office at her untimely departure. We were also saddened to learn of the demise of Dr R. Gwisai in June 2021 due to Covid. At the time of his death, Dr Gwisai was a member of Complementary Medicines and Registration Committees and also Chairperson of Percentage Discount Board. Previously he served as a Board member, Chairperson of the Human Resources Committee, Registration Committee member and also Pharmacovigilance and Clinical Trials Committee member. The Authority shall forever cherish the invaluable contributions made by the two members. May we continue to pray for their families to be consoled at the irreparable loss and may their dear souls continue to rest in eternal peace.

Annual General Meeting

The Authority held its 3rd Annual General Meeting on the 15th of October 2021 to approve the 2020 audited Financial Statements. The event was an opportunity for the Authority to assess and confirm that it had executed its mandate accordingly and also gave our principal stakeholders an opportunity to engage directly with the MCAZ Board Chairman and Acting Director-General.

Table 1

Board Committees

Below is a list of 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 2021: Meetings attended/held

	Committee	Members	Meetings attended/held	Responsibilities and Achievements
1.	Authority	Dr M. Chiware (Chairperson) Dr C Duri Dr C. Pasi 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 4/4 4/4 4/4 4/4 4/4 4/4 3/4 4/4 3/4	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. **Achievements during 2021:** • Approval of emergency use authorization for covid vaccines • Approval of the MCAZ Board Charter for submission to MOHCC in terms of the PECOGA requirements • Timely adoption of Board Committee reports and the Director-General's reports • Reviewed all issues brought to the attention of the Board.
2.	Registration	Dr C Duri (Chairperson) Dr C. Pasi Dr R. Chigwanda Prof C.C Maponga Dr M. Murwira Mr E. Mupanehari Dr D. Tagwireyi	16/16 14/16 16/16 16/16 12/1612/16 15/16	Oversight and statutory decision making on registration of medicines **Achievements during 2021:** • Provided timely approval of the EVR Annual Workplan • Directed successful implementation of the EVR Annual Workplan • Established a responsive risk-based approval system for Covid vaccines emergency use authorization • Established a responsive risk-based approval system for Covid therapeutics emergency use authorization • Took the final statutory decisions to either register or refuse registration of products

				• Ensured for all approved products the benefits outweighed the risk • Approved the MCAZ Small Business Support (SBS) plan for facilitating government's local production strategy • Approval of new policies and procedures needed for alignment with SADC Model Law and WHO Global Benchmarking Tool.
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	3/5 3/5 4/5 4/5 1/2 4/5 4/5 3/3	Gives guidance with respect to current quality standards for the laboratories and assists in the attainment and maintenance of such standards as required. Also focuses on the quality control testing of medicines and medical devices. **Achievements during 2021:** • Guided the laboratory units to produce standardized and streamlined reports resulting in effective laboratory committee meetings. • Reviewed all significant laboratory decisions that affect operations of the laboratory to ensure operational efficiency including reduced testing turnaround times. • Consistently reviewed laboratory decisions and proposed ideas on the most effective implementation and maintenance of laboratory quality management systems, hence the laboratory was able to maintain ISO/IEC 17025 accreditation and WHO prequalification status. • Contributed to the successful refurbishment and remodeling of the Microbiology laboratory in preparation for WHO prequalification inspection. • Providing oversight, technical expertise and leadership in the current project of setting up a cannabis and complementary medicines testing laboratory.
4.	PVCT	Dr C. Pasi (Chairperson) Dr C. Duri Dr T.R Bwakura Prof C.E Ndlovu Dr A. Mushavi	12/12 8/12 5/12 11/12 12/12	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-marketing surveillance.

		Mr N. Madzikwa Ms S Ruzario/ Mr T.A Kureya Prof D. Tagwireyi Dr R. Nyikadzino Mrs J. Chaibva	10/12 12/12 12/12 12/12	**Achievements during 2021:** • Achieved WHO Maturity Level 3 for the Clinical Trial Oversight function during the WHO GBT assessment • Provided timely review of new COVID-19 vaccine clinical trials applications and submitted recommendations to the Secretary for Health and Child Care • Successfully implemented safety monitoring activities for the approved COVID-19 vaccines in the country • New guidelines developed and approved, i.e. o Pharmacovigilance guideline for pharmaceutical industry : Rev 0 March 2021 o Guidelines for conducting Good Clinical Trial Inspections in Zimbabwe: Rev 0 May 2021 o Guideline for Pharmacovigilance of COVID-19 Vaccine AEFI Safety surveillance: Rev 0 May 2021 • Implemented an operational framework for the off-label use of ivermectin for COVID-19 • Consistently reviewed and took action on reported adverse event reports • Successfully achieved the revenue targets for the year 2021 • Successfully implemented risk mitigation measures in line with the PVCT risk register • Successfully implemented RCORE activities, e.g. trainings on PV and CT for other NRAs in the region • Successfully implemented donor-partner funded projects, e.g. GF HIV grant funding for PV activities high speed internet, 2x staff salaries etc. & CHAI PV trainings countrywide, EDCTP SPaRCS project & SEARCH project regional RCORE projects, PEI Vacc-Train , Uganda CT training & Namibia Training • Secured funding for the STARSS II project from the STARSS (I) Project University of Adelaide Australia for the IT server and nurses' remunerations, and achieved the enrolment target of 4500 participants.

5.	Veterinary	Dr E.O Waniwa (Chairperson) Dr S.L Mutambu Mrs J. Chaibva Dr C.T Hodobo Dr P. Muvavariwa Dr V.P Makaya Dr Ndengu Dr P.S Woods Dr F.T Makuvadze	5/6 4/6 6/6 4/6 5/6 3/6 6/6 6/6 5/6	Oversight and statutory decision making on registration of veterinary medicines **Achievements during 2021:** • Provided timely approval of the EVR Veterinary Medicines Subunit, Workplan • Directed successful implementation of the EVR Veterinary Medicines Subunit Workplan • Took the final statutory decisions to either register or refuse veterinary medicines based on safety, quality and efficacy considerations • Ensured for all approved products the benefits outweighed the risk • Guided staff in developing SADC joint assessment procedures
6.	Licensing	Dr M. Chiware (Chairperson) Mrs Y.M Zhou Dr A.F Zinanga Mrs M. Mothobi Ms R.C Makunike Mrs R. Mpofu- Chikarakara Mr N. Madzikwa	11/11 10/11 11/11 11/1111/11 8/11 10/11	Makes decisions on the outcome of inspection for new premises applications, routine inspections, advertising material and enforcement activities. Also decides on whether or not to issue a license/permit for premises and persons handling medicines
7.	Audit	Dr C. Mutisi Mr P. Mwendera Mr D. Mahofa	6/6 5/6 6/6	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.

		Mrs D. Shinya Adv N. Maphosa	4/6 6/6	**Achievements during 2021:** ● Directed successful implementation of the Risk Management Policy ● Re-established Fraud Management Committees for effective oversight of Deloitte Tip-offs platform ● Consistently reviewed and took action on significant audit findings reported to it by the Internal and External Auditors and Management. ● Actively followed up on implementation of audit recommendations including recoveries of prejudiced amounts. ● Reviewed financial statements before approval by the Board in order to ensure their objectivity, accuracy, and timely presentation. ● Provided timely approval of Internal Audit plans and budget ● Regularly evaluated the Authority's exposure to risk and fraud ● Reviewed all significant transactions especially those that are non-routine and those that may be questionable or unethical.
8.	Human Resources	Dr C. Duri (Chairperson) Mr E. Jinda Mrs F. Chinogurei Dr P. Muvavarirwa Mrs J. Ncube	4/4 4/4 2/4 3/4 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. **Achievements during 2021:** ● Holding all scheduled Committee meetings ● Continuous minimization of Covid-19 risks through regular education, communication, information strategies. ● Payment of monthly salaries and allowances to staff ● Upward review of employee remuneration, where sustainable ● Implementation of appropriate and relevant learning and development programs for staff. ● Maintaining a harmonious industrial relations climate ● Fostering a high-performance culture amongst employees and the business, etc.

9	Finance	Ms Y.M Zhou (Chairperson) Dr M. Chiware Mr I. Ruzengwe Mr C. Shonhiwa Dr A.Z Zinanga	4/5 5/5 4/5 4/5 5/5	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. **Achievements during 2021:** ● 2020 Financial Statements were certified ● Expenditure was within budget with the closing cash balance above US$200k as planned. ● Provided oversight for the costing of all MCAZ revenue lines and the production of a revised fee schedule based on costing.
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) Mrs J. Chaibva Mr S. Deme	 6/6 6/6 6/6 6/6 6/6 3/6 4/6 4/6	Providing guidance on all legal issues pertaining to the Authority, reviewing and drafting legislation and policies. **Achievements by the Legal Committee during 2021:** ● Finalized the review of the Board Charter, Legal Committee, Legal Drafting Sub-Committee and Hearing Committee Terms of Reference. ● Finalized the review of the Blood and Blood Components Regulations. ● Considered all matters that were referred to it from other Committees and Units and Divisions of the Authority. ● Managed and mitigated the Authority's exposure to legal risk through giving sound legal advice. ● Held all scheduled meetings **Achievements by the Legal Drafting Sub-Committee** Reviewed the Cosmetics Regulations ● Held all scheduled meetings

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	6/6 4/6 6/6 6/6 6/6 5/6 5/6 6/6	Oversight and statutory decision-making on registration of Complementary medicines **Achievements during 2021:** ● Provided timely approval of the EVR Complement Medicines SubUnit, Workplan ● Directed successful implementation of the EVR Complement Medicines SubUnit Workplan ● Established a responsive risk-based approval system for Complementary Medicines ● Took the final statutory decisions to either register or refuse complementary medicines based on safety, quality and efficacy considerations ● Ensure for all approved products the benefits outweighed the risk
12.	Controlled Substances	Dr C Duri (Chairperson) 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	1/1 1/1 1/1 1/1 1/1 1/1 1/1 1/1 1/1 1/1 1/1 1/1	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 **Achievements during 2021:** ● The inaugural meeting was done on the 19th of November 2021 ● Resolved that meetings be held once every quarter.

13.	Hearing	Mrs N. Samuriwo (Chairperson) Mr D.N Vuragu Prof C.C Maponga Mr. D Moyo Mrs J. Ncube	1/1 1/1 1/1	Conducts hearings into matters referred to it from the Licensing and Advertising Committee and make appropriate decisions for and on behalf of the Authority. **Achievements during 2021:** • Heard and disposed of four (4) matters referred to it. • Held all scheduled meetings.

Management

The Director-General leads Management in implementing Board decisions and keeping within the set strategy. Currently, Mr R T Rukwata is acting following the retirement of Ms Mahlangu in 2020. Duties of Management include making operational decisions, developing appropriate and relevant policies and recommendations as well as keeping the Board informed about MCAZ operations.

Below is the 2021 Management Team, although the Head-Chemistry, ICT Manager and Procurement & Administration Manager resigned during the course of 2021.

Table 2

	Name	Position
1.	Mr. R. T. Rukwata	Acting Director-General
2.	Dr. W. Wekwete	Head, Evaluations and Registration
3.	Mrs. P. P Nyambayo	Head, Pharmacovigilance and Clinical Trials
4.	Mrs. B Dube	Head, Chemistry
5.	Mr. R. T. Rukwata	Head, Licensing and Enforcement
6.	Mr. E Kulube	Head, Finance
7.	Dr. T Munhenga	Head, Human Resources
8.	Mrs. A Chikowore	Quality Manager
9.	Mr. T. A. Gonho	Manager, Microbiology and Medical Devices
10.	Ms. R Tugwete	Internal Auditor
11.	Mr. T Nyovhi	ICT Manager
12.	Mrs. R Gwata	Finance Manager
13.	Mr. F Tembo	Procurement and Administration Manager
14.	Mrs. C Samatanga	Chief Regulatory Officer, LED
15.	Ms. A Verenga	Chief Regulatory Officer, LED
16.	Mrs. T Makamure-Sithole	Projects and Public Relations Manager
17.	Mr. C Shamuyarira	Chief Analyst, Chemistry

Risk Management

The Authority has implemented a robust system for assessing, evaluating, measuring and mitigating risk at both operational and strategic levels in line with the Corporate Risk Policy. Functional Heads are responsible for monitoring risk within their units/divisions and update their unit risk registers on a quarterly basis. The Quality Unit monitors the unit risk registers to ensure implementation and effectiveness of actions taken to address risks and opportunities. Internal Audit 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.

During 2021, the Covid 19 pandemic was dominant on our risk profile, resulting in Management and the Board having to continuously reconsider strategies to sustain operations under the volatile and uncertain operating environment. The other dominant risk was the delayed approval of legislation which has significantly affected the registration process and ability for MCAZ to participate competitively on International bids.

Internal Audit Unit

The Internal Audit Unit assists the Audit Committee in its oversight role and helps the Board and Management to achieve set objectives by evaluating the adequacy of the system of internal controls, risk management and governance processes. 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 six audits were conducted in 2021 up from five conducted in 2020, with follow-up audits being conducted each quarter. The Internal Audit Unit also conducted a customer satisfaction survey during the 4th quarter of 2021 to get feedback from its internal customers on their experience with the Unit and attained an overall score of 83%.

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. To support these services, the Authority also developed a Whistleblowing Policy that provides clear procedures for the reporting of such matters, to ensure that all improper, unethical or inappropriate behaviour is identified and challenged at all levels of the organization.

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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, 2021

Report on the Audit of the Consolidated Financial Statements

I have audited the consolidated financial statements of the Medicines Control Authority of Zimbabwe and its subsidiary ("the Group") as set out on pages 7 to 30, which comprise the consolidated statement of financial position as at December 31, 2021, and the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in reserves and consolidated statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

Opinion on the Consolidated Financial Statements

In my opinion, the accompanying consolidated financial statements present fairly, in all material respects, the consolidated financial position of Medicines Control Authority of Zimbabwe as at December 31, 2021, 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, 2021, and its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRSs).

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS

for the year ended December 31, 2021

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, 2021. 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. The key audit matters noted below relate to the audit of the financial statements.

Key Audit Matter	How my audit addressed the Key Audit Matter
Revenue recognition, refer to note 3.6,14 and 15 to the Consolidated financial statements. The Group's revenue is generated from the Medicines control licensing and laboratory services. The Group recognized revenue amounting to ZW$ 766 581 641 for the year ended December 31, 2021. Revenue recognition is highly complex given the large number of service offerings and high volumes of transactions. The management exercise significant judgement in determining the appropriate basis of revenue recognition. As a result, there is significant risk that revenue may be omitted, recognised inaccurately or accounted for in the incorrect period. Therefore, recognition of revenue was considered to be a key audit matter.	My procedures to address the risk of material misstatement relating to revenue recognition included: • Tested the system (internal control) surrounding revenue. • Conducted substantive analytical procedures on revenue. • Scrutinised journals related to revenue to assess the timing and fair values of revenue recorded. • Evaluated the adequacy of the disclosures regarding the trade receivables Based on evidence gathered, I found that management's revenue recognition criteria was appropriate and revenue disclosures were appropriate.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS

for the year ended December 31, 2021

Key Audit Matter	How my audit addressed the Key Audit Matter
Valuation of investment property, refer to notes 3.1.4 and 5 to the financial statements. The Group's investment property fair value increased from ZW$ 132 948 898 to ZW$ 202 501100. Valuation of the investment property is subjective due to the use of judgments and estimates. The fair value was determined with reference to unobservable inputs which include rental per square metre, capitalisation rates and vacancy rates. The valuation has also been undertaken in an unstable economic environment which is characterised by rising inflation, liquidity challenges and frequent monetary policy changes. As a result of the magnitude of the investment property balance and the significant 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 whether there is adequate documentation /policy to support the assumptions that investment properties reflect the existing economic conditions and existing business circumstances. • Reviewed the assumptions used for valuation of investment property carried at fair value. • Reviewed whether the basis of assumptions used comply with 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 notes 3.1.3 and 4 to the financial statements. The Group held property, plant and equipment with revalued carrying amount of ZW$619 735 381 as at December 31,2021 after adjusting for revaluation surplus of ZW$149 250 634. The valuation of the property, plant and equipment was dependent on the valuation methodology adopted and the inputs into the valuation model. The valuation took into account unobservable inputs and therefore requires significant judgement in determining the values of the assets. As a result, valuation of property, plant and equipment was considered to be 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 whether there is adequate documentation /policy to support the assumptions that property, plant and equipment reflect the existing economic conditions and existing business circumstances. • Reviewed the assumptions used for revaluation of property, plant and equipment. • Reviewed whether the revaluation was in compliance with IAS 16. Based on the evidence gathered, I found that the Group's property, plant and equipment was appropriately valued and adequate disclosures related to property, plant and equipment in the financial statements were appropriate.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS

for the year ended December 31, 2021

Other Information

The directors are responsible for the Other Information. The Other Information comprises all the information in the Medicines Control Authority of Zimbabwe's 2021 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 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 financial statements, management is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Group or cease operations or has no realistic alternative but to do so.

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

Auditor's Responsibilities for the Audit of the Financial Statements

The objectives of my audit are to obtain reasonable assurance about whether the 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's 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 financial statements.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS

for the year ended December 31, 2021

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 financial statements, including the disclosure, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

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.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

AUDIT REPORT IN RESPECT OF THE FINANCIAL STATEMENTS

for the year ended December 31, 2021

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*], and other relevant Statutory Instruments.

September 26, 2022.

L. CHIKOWORE,
ACTING AUDITOR-GENERAL.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

as at December 31, 2021

		MCAZ GROUP				AUTHORITY			
		Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	Note	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$
ASSETS									
Non-current assets		**822 236 481**	**619 780 106**	**805 364 584**	**179 499 892**	**783 381 219**	**583 179 129**	**746 877 087**	**145 021 878**
Property, plant and equipment	4	619 735 381	486 831 208	602 863 484	96 789 132	560 941 258	430 961 382	544 157 392	62 092 523
Investment property	5	202 501 100	132 948 898	202 501 100	82 710 760	202 501 100	132 948 898	202 501 100	82 710 760
Investment in subsidiary	6	-	-	-	-	19 938 861	19 268 849	218 595	218 595
Current assets		**548 397 399**	**509 777 401**	**548 369 797**	**316 710 222**	**544 394 370**	**507 041 093**	**544 366 768**	**315 007 898**
Inventories	7	2 071 639	2 041 608	2 044 037	835 371	2 071 639	2 041 608	2 044 037	835 371
Trade and other receivables	8	21 197 164	25 108 004	21 197 164	15 620 303	21 121 627	25 012 042	21 121 627	15 560 603
Cash and cash equivalents	9	525 128 596	482 627 789	525 128 596	300 254 548	521 201 104	479 987 443	521 201 104	298 611 924
Total assets		**1 370 633 880**	**1 129 557 507**	**1 353 734 381**	**496 210 114**	**1 327 775 589**	**1 090 220 222**	**1 291 243 855**	**460 029 776**
RESERVES AND LIABILITIES									
Reserves		**1 116 203 857**	**901 322 034**	**1 204 659 653**	**415 669 394**	**1 087 511 351**	**873 593 696**	**1 156 334 912**	**386 711 265**
Capital reserve		379 888 861	379 888 861	5 444 017	5 444 017	379 888 861	379 888 861	5 444 017	5 444 017
Accumulated fund		303 139 090	233 696 769	526 564 516	219 180 578	315 896 281	244 767 120	626 407 660	320 220 086
Revaluation reserve		306 746 541	161 977 054	550 681 035	77 015 025	391 726 209	248 937 715	524 483 235	61 047 162
Non-controlling interest		126 429 365	125 759 350	121 970 085	114 029 774	-	-	-	-
Non-current liabilities		**133 930 474**	**100 630 865**	**28 575 179**	**9 471 836**	**119 770 122**	**89 029 814**	**14 414 827**	**2 254 538**
Deferred income	10	119 770 122	89 029 814	14 414 827	2 254 538	119 770 122	89 029 814	14 414 827	2 254 538
Deferred tax	11	14 160 352	11 601 051	14 160 352	7 217 298	-	-	-	-
Current liabilities		**120 499 549**	**127 604 608**	**120 499 549**	**71 068 884**	**120 494 116**	**127 596 712**	**120 494 116**	**71 063 973**
Trade and other payables	12	115 372 008	112 682 071	115 372 008	70 102 270	115 366 575	112 674 175	115 366 575	70 097 359
Provisions	13	3 854 001	1 128 022	3 854 001	701 770	3 854 001	1 128 022	3 854 001	701 770
Deferred income	10	1 273 540	13,794,515.0	1 273 540	264,844.0	1 273 540	13,794,515.0	1 273 540	264,844.0
Total reserves and liabilities		**1 370 633 880**	**1 129 557 507**	**1 353 734 381**	**496 210 114**	**1 327 775 589**	**1 090 220 222**	**1 291 243 855**	**460 029 776**

16/9/22 , 2022.

16/09/2022 , 2022.

16/09 , 2022.

E. Kulube,
Msc Strategic Management, Bcom. Accounting,
(HEAD FINANCE AND BUSINESS SUPPORT).

R. Rukwata,
(ACTING 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	
		2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$
INCOME		**766 581 641**	**775 777 717**	**691 448 951**	**443 312 484**	**762 279 751**	**770 662 780**	**687 892 548**	**440 951 460**
Medicines control income	14	470 741 539	317 004 816	368 374 698	135 039 902	470 741 539	317 004 816	368 374 698	135 039 902
Laboratory services	15	92 833 984	78 117 792	77 552 513	34 111 949	92 833 984	78 117 792	77 552 513	34 111 949
Other income	16	203 006 118	380 655 109	245 521 740	274 160 633	198 704 228	375 540 172	241 965 337	271 799 609
LESS EXPENDITURE		**510 269 569**	**509 101 560**	**382 820 344**	**192 588 894**	**508 868 004**	**507 595 762**	**381 704 974**	**191 994 231**
Other expenses	18	307 026 049	305 072 261	250 214 435	137 196 088	307 026 049	305 072 261	250 214 435	137 196 088
Administration expenses	17	203 243 520	204 029 299	132 605 909	55 392 806	201 841 955	202 523 501	131 490 539	54 798 143
Surplus for the year		**256 312 072**	**266 676 157**	**308 628 607**	**250 723 590**	**253 411 747**	**263 067 018**	**306 187 574**	**248 957 229**
Monetary loss		**(187 163 061)**	**(324 930 350)**	**-**	**-**	**(182 282 586)**	**(320 195 255)**	**-**	**-**
Surplus/(deficit) before taxation		**69 149 011**	**(58 254 193)**	**308 628 607**	**250 723 590**	**71 129 161**	**(57 128 237)**	**306 187 574**	**248 957 229**
Taxation		(413 298)	(418 230)	(413 298)	(260 191)	-	-	-	-
Surplus/(deficit) after taxation		**68 735 713**	**(58 672 423)**	**308 215 309**	**250 463 399**	**71 129 161**	**(57 128 237)**	**306 187 574**	**248 957 229**
Other comprehensive income									
Revaluation gain/(loss)		149 250 634	(10 613 130)	480 968 076	18 243 231	145 893 018	-	463 629 199	
Total other comprehensive income		**149 250 634**	**(10 613 130)**	**480 968 076**	**18 243 231**	**145 893 018**	**-**	**463 629 199**	**-**
Total comprehensive income/(loss)		**217 986 347**	**(69 285 553)**	**789 183 385**	**268 706 630**	**217 022 179**	**(57 128 237)**	**769 816 773**	**248 957 229**
Surplus attributable to:									
Equity holders of the parent		69 442 321	(58 799 175)	307 383 938	147 773 405	71 129 161	(57 128 237)	306 187 574	248 957 229
Non-controlling interest		(706 608)	126 752	831 371	102 689 994	-	-	-	-
Surplus/(deficit) for the year		**68 735 713**	**(58 672 423)**	**308 215 309**	**250 463 399**	**71 129 161**	**(57 128 237)**	**306 187 574**	**248 957 229**
Other comprehensive income attributable to:									
Equity holders of the parent		147 874 011	(6 261 747)	473 859 136	10 763 503	145 893 018	-	463 629 199	-
Non-controlling interest		1 376 623	(4 351 383)	7 108 940	7 479 728	-	-	-	-
Surplus/(deficit) for the year		**149 250 634**	**(10 613 130)**	**480 968 076**	**18 243 231**	**145 893 018**	**-**	**463 629 199**	**-**

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

STATEMENT OF CHANGES IN RESERVES

for the year ended December 31, 2021

Group Inflation adjusted	Accumulated fund	Capital reserve	Revaluation reserve	Total	Non-controlling interest	Total reserves
	ZW$	ZW$	ZW$	ZW$	ZW$	ZW$
Balance as at January 1, 2020	**292 495 944**	**379 888 861**	**168 238 801**	**840 623 606**	**129 983 981**	**970 607 587**
Deficit for the year	(58 799 175)	-	-	**(58 799 175)**	126 752	**(58 672 423)**
Other comprehensive income	-	-	(6 261 747)	**(6 261 747)**	(4 351 383)	**(10 613 130)**
Balance as at December 31, 2020	**233 696 769**	**379 888 861**	**161 977 054**	**775 562 684**	**125 759 350**	**901 322 034**
Balance as at January 1, 2021	**233 696 769**	**379 888 861**	**161 977 054**	**775 562 684**	**125 759 350**	**901 322 034**
Surplus/(deficit) for the year	69 442 321	-	-	**69 442 321**	(706 608)	**68 735 713**
Revaluation surplus	-	-	147 874 011	**147 874 011**	1 376 623	**149 250 634**
Elimination of realised gain on disposed asset	-	-	(3 104 524)	**(3 104 524)**	-	**(3 104 524)**
Balance as at December 31, 2021	**303 139 090**	**379 888 861**	**306 746 541**	**989 774 492**	**126 429 365**	**1 116 203 857**

Historical cost	Accumulated fund	Capital reserve	Revaluation reserve	Total	Non controlling interest	Total reserves
	ZW$	ZW$	ZW$	ZW$	ZW$	ZW$
Balance as at January 1, 2020	**71 407 173**	**5 444 017**	**66 251 522**	**143 102 712**	**3 860 052**	**146 962 764**
Surplus for the year	147 773 405	-	-	**147 773 405**	102 689 994	**250 463 399**
Revaluation surplus	-	-	10 763 503	**10 763 503**	7 479 728	**18 243 231**
Balance as at December 31, 2020	**219 180 578**	**5 444 017**	**77 015 025**	**301 639 620**	**114 029 774**	**415 669 394**
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 disposed asset	-	-	(193 126)	**(93 126)**	-	**(193 126)**
Balance as at December 31, 2021	**526 564 516**	**5 444 017**	**550 681 035**	**1 082 789 568**	**121 970 085**	**1 204 659 653**

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

STATEMENT OF CHANGES IN RESERVES

for the year ended December 31, 2021

Authority Inflation adjusted	Accumulated fund ZW$	Capital reserve ZW$	Revaluation reserve ZW$	Total ZW$
Balance as at January 1, 2020	301 895 357	379 888 861	248 937 715	**930 721 933**
Deficit for the year	(57 128 237)	-	-	(57 128 237)
Balance as at December 31, 2020	**244 767 120**	**379 888 861**	**248 937 715**	**873 593 696**
Balance as at January 1, 2021	**244 767 120**	**379 888 861**	**248 937 715**	**873 593 696**
Surplus for the year	71 129 161	-	-	**71 129 161**
Revaluation surplus	-	-	145 893 018	**145 893 018**
Elimination of realised gain on disposed asset	-	-	(3 104 524)	**(3 104 524)**
Balance as at December 31, 2021	**315 896 281**	**379 888 861**	**391 726 209**	**1 087 511 351**

Authority Historical cost	Accumulated fund ZW$	Capital reserve ZW$	Revaluation reserve ZW$	Total ZW$
Balance as at January 1, 2020	71 262 857	5 444 017	61 047 162	**137 754 036**
Surplus for the year	248 957 229	-	-	**248 957 229**
Balance as at December 31, 2020	**320 220 086**	**5 444 017**	**61 047 162**	**386 711 265**
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 disposed asset	-	-	(193 126)	**(193 126)**
Balance as at December 31, 2021	**626 407 660**	**5 444 017**	**524 483 235**	**1 156 334 912**

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

CONSOLIDATED STATEMENT OF CASH FLOWS

for the year ended December 31, 2021

		MCAZ GROUP				AUTHORITY			
		Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	Note	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$
Net cash flow from operating activities		**(27 406 597)**	**(174 000 136)**	**151 824 140**	**215 611 594**	**(29 186 093)**	**(177 184 364)**	**149 045 828**	**214 316 668**
Surplus/(deficit) for the year		69 149 011	(58 254 193)	308 628 607	250 723 590	71 129 161	(57 128 237)	306 187 574	248 957 229
Adjusted for non cash items:		**(105 852 333)**	**(181 053 736)**	**(195 304 515)**	**(86 024 669)**	**(109 594 017)**	**(184 422 504)**	**(195 641 272)**	**(85 366 425)**
Depreciation for the year	4	50 501 835	41 459 165	7 223 148	4 137 157	50 068 516	41 025 846	6 879 917	4 080 264
Increase/(decrease) in provision for leave pay	13	2 725 979	(52 253)	3 152 231	538 090	2 725 979	(52 253)	3 152 231	538 090
Fair value adjustment on investment property	5	(69 552 202)	53 573 210	(119 790 340)	(56 843 860)	(69 552 202)	53 573 210	(119 790 340)	(56 843 860)
Deferred income amortisation	10	(1 986 265)	(13 794 515)	(1 380 524)	(264 844)	(1 986 265)	(13 794 515)	(1 380 524)	(264 844)
Loss on disposal of property, plant and equipment	17	195 839	-	173 581	-	195 839	-	173 581	-
Adjustment of duplicated assets	4	11 698	-	73 962	-	11 698	-	73 962	-
Realised gain on disposed asset	16	(3 104 524)	-	(193 126)	-	(3 104 524)	-	(193 126)	-
Interest earned	16	(8 935)	(67 591)	(7 440)	(15 326)	(1 367)	(64 667)	(966)	(13 647)
Exchange gains-unrealised		(84 556 007)	(273 869 929)	(84 556 007)	(33 575 886)	(84 556 007)	(273 869 929)	(84 556 007)	(32 862 428)
Net monetary gain/(loss)		(79 751)	11 698 177	-	-	(3 395 684)	8 759 804	-	-
Working capital changes:		**9 296 725**	**65 307 793**	**38 500 048**	**50 912 673**	**9 278 763**	**64 366 377**	**38 499 526**	**50 725 864**
(Increase)/decrease in inventories	7	(30 031)	283 506	(1 208 666)	(540 918)	(30 031)	283 506	(1 208 666)	(540 918)
(Increase)/decrease in trade and other receivables	8	3 910 840	(3 801 143)	(5 561 024)	(12 605 766)	3 890 415	(3 705 182)	(5 561 024)	(12 605 766)
Increase in trade and other payables	12	5 415 916	68 825 430	45 269 738	64 059 357	5 418 379	67 788 053	45 269 216	63 872 548
Income tax paid	11.2	(499 918)	(603 187)	(499 918)	(375 258)	-	-	-	-
Net cash flow from investing activities:		**(14 148 685)**	**(4 991 424)**	**(11 006 181)**	**(2 414 443)**	**(14 156 253)**	**(4 994 348)**	**(11 012 655)**	**(2 416 122)**
Purchase of property, plant and equipment	4	(14 821 295)	(5 059 015)	(11 037 871)	(2 429 769)	(14 821 295)	(5 059 015)	(11 037 871)	(2 429 769)
Proceeds from disposal of property, plant and equipment		663 675	-	24 251	-	663 675	-	24 251	-
Interest received	17	8 935	67 591	7 440	15 326	1 367	64 667	966	13 647
Net (decrease)/increase in cash and cash equivalents		**(42 055 200)**	**(179 594 747)**	**140 318 042**	**212 821 893**	**(43 342 346)**	**(182 178 712)**	**138 033 174**	**211 900 546**
Exchange gains on cash and cash equivalents		**84 556 007**	**273 869 929**	**84 556 007**	**33 575 886**	**84 556 007**	**273 869 929**	**84 556 007**	**32 862 428**
Cash and cash equivalents at beginning of the year		**482 627 789**	**388 352 607**	**300 254 548**	**53 856 769**	**479 987 443**	**388 296 226**	**298 611 924**	**53 848 950**
Cash and cash equivalents at year end	9	**525 128 596**	**482 627 789**	**525 128 596**	**300 254 548**	**521 201 104**	**479 987 443**	**521 201 104**	**298 611 924**

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2021

1. NATURE OF BUSINESS.

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

2. BASIS OF PREPARATION

2.1 Statement of compliance

The Group's financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and interpretations issued by the IFRS Interpretations Committee ("IFRS IC") as issued by the International Accounting Standards Board ("IASB").

The Group's financial statements for the 2020 reporting period were qualified based on the residual effects of IAS 21, on the 2019 opening balances. Management made an assessment on the impact of 2019 foreign currency denominated opening balances on its current year financial statements and believe that there are no misstatements as a result of opening balances in the current year as supported by the following facts and circumstances:

- The Authority receives the Foreign Income from collection of Revenue from Registration fees, Retention fees and Good Manufacturing Practice (GMP) Inspection fees.
- The Group's Foreign Income has been translated using the Reserve Bank of Zimbabwe auction rate.
- The Group translates all transactions at the exchange rates prevailing at the time of transacting while year end balances are translated at the closing rate at the end of the reporting period satisfying the requirements of IAS21.This is line with Statutory Instrument 85 of 2020 which allows goods and services chargeable in Zimbabwe dollars to be paid in foreign currency using free funds at the ruling rate on the date of payment.
- Some of the funds received in 2019 were utilised in the operations of the Group.
- All of the Group's assets are revalued yearly by an independent valuation company in both currencies US$ and ZWL$. The assets were valued at fair value using the prevailing ZWL$ market rates.
- All items that were part of stock balances from 2019 were consumed in 2020 and did not form part of 2021 the balances.

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 (ZW$) currency as prescribed under Statutory Instrument 33 of 2019 dated 22nd February 2019 and in Statutory Instrument 142 of 2019 dated 24th June 2019. The Authority adopted the Zimbabwe Dollar (ZW$) 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.

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.

Month	Index	Conversion Factor
December 2021	3977.50	1
December 2020	2474.50	1.61
December 2019	551.6	7.21

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 reviewed on an ongoing basis. Revisions to accounting estimates are recognised 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.

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.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended December 31, 2021

2.6 Amended Standards – Effective 1 January 2021

i. **Amendment to 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 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 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.

iv. **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.

2.8 Basis of Consolidation

2.8.1 Group

The consolidated financial statements comprise the financial statements of the Group and its 59% stake in the subsidiary – Percentage Discount (Private) Limited, as at December 31,2021.

2.8.2 Subsidiary

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

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

All intra group balances, income, expenses, unrealized gains, and losses resulting from intra-group transactions are eliminated in full on consolidation. In all material respects, the accounting policies of the 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.

2.8.2.1 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.

2.8.2.2 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, 2021

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, 2020.

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	33.33%
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.

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.

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

IFRS 16 introduced new or amended requirements with respect to lease accounting. 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, Mishonga Gardens. 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.

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.

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 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 Inventories

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.
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.

3.7 **Employment benefits**

Defined contribution plan

A defined contribution plan is a post- employment benefit plan under which the Group pays fixed contributions into separate entity and has no legal or constructive obligation to pay further amounts. Obligations for contributions to defined contribution plans are recognised as an employee benefit expense in profit or loss in the period during which related services are rendered by employees.

MCAZ GROUP

4 Property, plant and equipment

Inflation adjusted	Freehold land ZW$	Buildings ZW$	Plant and machinery ZW$	Motor vehicles ZW$	Computer and equipment ZW$	Office equipment ZW$	Furniture and fittings ZW$	Work in progress ZW$	Total 2021 ZW$	Total 2020 ZW$
Opening carrying amount	**189 324 311**	**190 321 593**	**70 110 546**	**11 207 007**	**(141 942)**	**(123 130)**	**9 331 667**	**16 801 156**	**486 831 208**	**533 844 488**
Gross carrying amount	189 324 311	223 272 948	88 487 683	30 529 832	25 475 123	6 020 385	12 457 210	16 801 156	592 368 648	597 922 763
Accumulated depreciation	-	(32 951 355)	(18 377 137)	(19 322 825)	(25 617 065)	(6 143 515)	(3 125 543)	-	(105 537 440)	(64 078 275)
Additions at cost	-	-	-	301 829	10 402 948	2 212 541	1 185 285	718 692	**14 821 295**	**5 059 015**
Donated assets at cost	-	-	18 623 001	-	1 582 290	-	-	-	**20 205 291**	-
Duplicated assets	**-**	**-**	**3 279**	**(68)**	**(8 394)**	**-**	**(6 515)**	**-**	**(11 698)**	**-**
Gross carrying amount	-	-	-	-	(1 209 483)	-	(23 613)	-	(1 233 096)	-
Accumulated depreciation	-	-	3 279	(68)	1 201 089	-	17 098	-	1 221 398	-
Revaluation	**(6 101 211)**	**125 206 375**	**2 851 760**	**5 481 248**	**12 806 681**	**7 081 789**	**1 923 992**	**-**	**149 250 634**	**(10 613 130)**
Gross carrying amount	(6 101 211)	125 206 375	2 851 760	5 481 248	12 806 681	7 081 789	1 923 992	-	149 250 634	(10 613 130)
Accumulated depreciation	-	-	-	-	-	-	-	-	-	-
Disposals carrying amount	**-**	**-**	**-**	**(777 077)**	**(82 437)**	**-**	**-**	**-**	**(859 514)**	**-**
Disposals at cost	-	-	-	(4 927 962)	(109 916)	-	-	-	(5 037 878)	-
Accumulated depreciation	-	-	-	4 150 885	27 479	-	-	-	4 178 364	-
Depreciation for the year	-	(5 525 068)	(18 142 808)	(8 832 068)	(13 724 789)	(2 347 204)	(1 929 898)	-	**(50 501 835)**	**(41 459 165)**
Closing carrying amount	**183 223 100**	**310 002 900**	**73 445 778**	**7 380 871**	**10 834 357**	**6 823 996**	**10 504 531**	**17 519 848**	**619 735 381**	**486 831 208**
Gross carrying amount	183 223 100	348 479 323	109 962 444	31 384 947	48 947 643	15 314 715	15 542 874	17 519 848	770 374 894	592 368 648
Accumulated depreciation	-	(38 476 423)	(36 516 666)	(24 004 076)	(38 113 286)	(8 490 719)	(5 038 343)	-	(150 639 513)	(105 537 440)

Historical cost

	Freehold land ZW$	Buildings ZW$	Plant and machinery ZW$	Motor vehicles ZW$	Computer and equipment ZW$	Office equipment ZW$	Furniture and fittings ZW$	Work in progress ZW$	Total 2021 ZW$	Total 2020 ZW$
Opening carrying amount	**45 150 111**	**34 660 355**	**10 587 751**	**1 802 174**	**1 440 807**	**963 026**	**1 581 677**	**603 231**	**96 789 132**	**73 021 927**
Gross carrying amount	45 150 111	40 519 487	29 911 906	13 960 016	5 986 053	2 349 326	4 205 068	603 231	142 685 198	114 780 836
Accumulated depreciation	-	(5 859 132)	(19 324 155)	(12 157 842)	(4 545 246)	(1 386 300)	(2 623 391)	-	(45 896 066)	(41 758 909)
Additions at cost	-	-	-	285 390	7 677 691	1 884 364	1 074 965	115 461	**11 037 871**	**2 429 769**
Donated assets at cost	-	-	13 460 286	-	1 089 223	-	-	-	**14 549 509**	-
Duplicated assets	**-**	**-**	**2 040**	**(42)**	**(71 907)**	**-**	**(4 053)**	**-**	**(73 962)**	**-**
Gross carrying amount	-	-	-	-	(284 200)	-	(14 690)	-	(298 890)	-
Accumulated depreciation	-	-	2 040	(42)	212 293	-	10 637	-	224 928	-
Revaluation	**138 072 990**	**276 307 891**	**52 518 515**	**5 904 838**	**2 703 835**	**4 412 579**	**8 061 265**	**-**	**487 981 913**	**25 474 593**
Gross carrying amount	138 072 990	351 514 347	53 836 262	43 850 849	5 391 937	134 266 987	28 774 522	-	755 707 894	25 474 593
Accumulated depreciation	-	(75 206 456)	(1 317 747)	(37 946 011)	(2 688 102)	(129 854 408)	(20 713 257)	-	(267 725 981)	-
Disposals carrying amount	**-**	**-**	**-**	**(125 400)**	**(72 431)**	**-**	**-**	**-**	**(197 831)**	**-**
Disposals at cost	-	-	-	(2 253 351)	(80 225)	-	-	-	(2 333 576)	-
Accumulated depreciation	-	-	-	2 127 951	7 794	-	-	-	2 135 745	-
Depreciation for the year	-	(965 345)	(3 214 125)	(486 023)	(1 918 874)	(435 972)	(202 809)	-	**(7 223 148)**	**(4 137 157)**
Closing 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)

Included in property, plant and equipment is a property in Queensdale Township, Harare which the Authority has control and enjoys economic benefits. The property was not transferred into the name of Medicines Control Authority of Zimbabwe from the Ministry of Local Government and Public Works when the other properties from the Drugs Control Council were transferred in 1997.

AUTHORITY

4.1 Property, plant and equipment

Inflation adjusted	Freehold land ZW$	Buildings ZW$	Plant and machinery ZW$	Motor vehicles ZW$	Computer and equipment ZW$	Office equipment ZW$	Furniture and fittings ZW$	Work in progress ZW$	Total 2021 ZW$	Total 2020 ZW$
Opening carrying amount	**150 241 013**	**173 639 826**	**70 005 785**	**11 207 007**	**(141 942)**	**(123 130)**	**9 331 667**	**16 801 156**	**430 961 382**	**466 928 213**
Gross carrying amount	150 241 013	204 207 485	88 353 302	30 529 832	25 475 123	6 020 385	12 457 210	16 801 156	534 085 506	529 026 491
Accumulated depreciation	-	(30 567 659)	(18 347 517)	(19 322 825)	(25 617 065)	(6 143 515)	(3 125 543)	-	(103 124 124)	(62 098 278)
Additions at cost	-	-	-	301 829	10 402 948	2 212 541	1 185 285	718 692	**14 821 295**	**5 059 015**
Donated assets at cost	-	-	18 623 001	-	1 582 290	-	-	-	**20 205 291**	-
Duplicated assets	-	-	**3 279**	**(68)**	**(8 394)**	-	**(6 515)**	-	**(11 698)**	-
Gross carrying amount	-	-	-	-	(1 209 483)	-	(23 613)	-	(1 233 096)	-
Accumulated depreciation	-	-	3 279	(68)	1 201 089	-	17 098	-	1 221 398	-
Revaluation	**(10 155 413)**	**125 902 961**	**2 851 760**	**5 481 248**	**12 806 681**	**7 081 789**	**1 923 992**	-	**145 893 018**	-
Gross carrying amount	(10 155 413)	125 902 961	2 851 760	5 481 248	12 806 681	7 081 789	1 923 992	-	145 893 018	-
Accumulated depreciation	-	-	-	-	-	-	-	-	-	-
Disposals carrying amount	-	-	-	**(777 077)**	**(82 437)**	-	-	-	**(859 514)**	-
Disposals at cost	-	-	-	(4 927 962)	(109 916)	-	-	-	(5 037 878)	-
Accumulated depreciation	-	-	-	4 150 885	27 479	-	-	-	4 178 364	-
Depreciation for the year	-	(5 105 187)	(18 129 370)	(8 832 068)	(13 724 789)	(2 347 204)	(1 929 898)	-	**(50 068 516)**	**(41 025 846)**
Closing carrying amount	**140 085 600**	**294 437 600**	**73 354 455**	**7 380 871**	**10 834 357**	**6 823 996**	**10 504 531**	**17 519 848**	**560 941 258**	**430 961 382**
Gross carrying amount	140 085 600	330 110 446	109 828 063	31 384 947	48 947 643	15 314 715	15 542 874	17 519 848	708 734 136	534 085 506
Accumulated depreciation	-	(35 672 846)	(36 473 608)	(24 004 076)	(38 113 286)	(8 490 719)	(5 038 343)	-	(147 792 878)	(103 124 124)

Historical cost

	Freehold land ZW$	Buildings ZW$	Plant and machinery ZW$	Motor vehicles ZW$	Computer and equipment ZW$	Office equipment ZW$	Furniture and fittings ZW$	Work in progress ZW$	Total 2021 ZW$	Total 2020 ZW$
Opening carrying amount	**20 835 436**	**24 282 219**	**10 583 953**	**1 802 174**	**1 440 807**	**963 026**	**1 581 677**	**603 231**	**62 092 523**	**63 743 018**
Gross carrying amount	20 835 436	29 915 806	29 906 841	13 960 016	5 986 053	2 349 326	4 205 068	603 231	107 761 777	105 332 008
Accumulated depreciation	-	(5 633 587)	(19 322 888)	(12 157 842)	(4 545 246)	(1 386 300)	(2 623 391)	-	(45 669 254)	(41 588 990)
Additions at cost	-	-	-	285 390	7 677 691	1 884 364	1 074 965	115 461	**11 037 871**	**2 429 769**
Donated assets at cost	-	-	13 460 286	-	1 089 223	-	-	-	**14 549 509**	-
Duplicated Assets	-	-	**2 040**	**(42)**	**(71 907)**	-	**(4 053)**	-	**(73 962)**	-
Gross carrying amount	-	-	-		(284 200)	-	(14 690)	-	(298 890)	-
Accumulated depreciation	-	-	2 040	(42)	212 293	-	10 637	-	224 928	-
Revaluation	**119 250 165**	**270 778 002**	**52 518 515**	**5 904 838**	**2 703 835**	**4 412 579**	**8 061 265**	-	**463 629 199**	-
Gross carrying amount	119 250 165	345 984 458	53 836 262	43 850 849	5 391 937	134 266 987	28 774 522	-	731 355 180	-
Accumulated depreciation	-	(75 206 456)	(1 317 747)	(37 946 011)	(2 688 102)	(129 854 408)	(20 713 257)	-	(267 725 981)	-
Disposals carrying amount	-	-	-	**(125 400)**	**(72 431)**	-	-	-	**(197 831)**	-
Gross carrying amount	-	-	-	(2 253 351)	(80 225)	-	-	-	(2 333 576)	-
Accumulated depreciation	-	-	-	2 127 951	7 794	-	-	-	2 135 745	-
Depreciation for the year	-	(622 621)	(3 213 618)	(486 023)	(1 918 874)	(435 972)	(202 809)	-	**(6 879 917)**	**(4 080 264)**
Closing 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)

Included in property, plant and equipment is a property in Queensdale Township, Harare which the Authority has control and enjoys economic benefits. The property was not transferred into the name of Medicines Control Authority of Zimbabwe from the Ministry of Local Government and Public Works when the other properties from the Drugs Control Council were transferred in 1997.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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for the year ended December 31, 2021

	MCAZ GROUP				AUTHORITY			
	Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$
5 Investment property								
Opening fair value	**132 948 898**	**186 522 108**	**82 710 760**	**25 866 900**	**132 948 898**	**186 522 108**	**82 710 760**	**25 866 900**
Fair value adjustment	69 552 202	(53 573 210)	119 790 340	56 843 860	69 552 202	(53 573 210)	119 790 340	56 843 860
Closing value	**202 501 100**	**132 948 898**	**202 501 100**	**82 710 760**	**202 501 100**	**132 948 898**	**202 501 100**	**82 710 760**
6 Investment in subsidiary								
Percentage Discount (Pvt) Ltd	-	-	-	-	19 938 861	19 268 849	218 595	218 595
	-	-	-	-	**19 938 861**	**19 268 849**	**218 595**	**218 595**
7 Inventories								
Fuel	1 160 360	751 184	1 160 360	467 330	1 160 360	751 184	1 160 360	467 330
Provisions	324 017	271 859	283 313	156 471	324 017	271 859	283 313	156 471
Stationery consumables	587 262	1 018 565	600 364	211 570	587 262	1 018 565	600 364	211 570
	2 071 639	**2 041 608**	**2 044 037**	**835 371**	**2 071 639**	**2 041 608**	**2 044 037**	**835 371**
8 Trade and other receivables								
Trade receivables	34 982 273	18 138 795	34 982 273	11 284 588	34 982 273	18 138 795	34 982 273	11 284 588
Allowance for credit losses	(20 647 065)	(100 128)	(20 647 065)	(62 292)	(20 647 065)	(100 128)	(20 647 065)	(62 292)
	14 335 208	**18 038 667**	**14 335 208**	**11 222 296**	**14 335 208**	**18 038 667**	**14 335 208**	**11 222 296**
Other receivables	6 762 981	6 814 556	6 762 981	4 239 502	6 762 981	6 814 556	6 762 981	4 239 502
Rentals-Mishonga gardens	-	46 145	-	28 708	-	46 145	-	28 708
Staff receivables	-	52 498	-	32 660	-	52 498	-	32 660
Short term investments	23 438	60 176	23 438	37 437	23 438	60 176	23 438	37 437
Tax receivable	75 537	95 962	75 537	59 700	-	-	-	-
	21 197 164	**25 108 004**	**21 197 164**	**15 620 303**	**21 121 627**	**25 012 042**	**21 121 627**	**15 560 603**
9 Cash and cash equivalents								
Bank	525 128 026	482 627 128	525 128 026	300 254 137	521 200 534	479 986 782	521 200 534	298 611 513
Funds on placement	570	661	570	411	570	661	570	411
	525 128 596	**482 627 789**	**525 128 596**	**300 254 548**	**521 201 104**	**479 987 443**	**521 201 104**	**298 611 924**
10 Deferred income								
Opening carrying amount	**102 824 329**	**116 618 844**	**2 519 382**	**2 784 226**	**102 824 329**	**116 618 844**	**2 519 382**	**2 784 226**
Balance as at January 1, 2021	114 153 266	119 931 283	2 784 226	2 863 309	114 153 266	119 931 283	2 784 226	2 863 309
Accumulated amortisation	(11 328 937)	(3 312 439)	(264 844)	(79 083)	(11 328 937)	(3 312 439)	(264 844)	(79 083)
Additions	20 205 598	-	14 549 509	-	20 205 598	-	14 549 509	-
Amortisation charge for the year	(1 986 265)	(13 794 515)	(1 380 524)	(264 844)	(1 986 265)	(13 794 515)	(1 380 524)	(264 844)
Closing carrying amount	**121 043 662**	**102 824 329**	**15 688 367**	**2 519 382**	**121 043 662**	**102 824 329**	**15 688 367**	**2 519 382**
Balance as at January 31, 2021	134 358 864	119 931 283	17 333 735	2 863 309	134 358 864	119 931 283	17 333 735	2 863 309
Accumulated amortisation	(13 315 202)	(17 106 954)	(1 645 368)	(343 927)	(13 315 202)	(17 106 954)	(1 645 368)	(343 927)
Analysis of carrying amount	**121 043 662**	**102 824 329**	**15 688 367**	**2 519 382**	**121 043 662**	**102 824 329**	**15 688 367**	**2 519 382**
Non- current	119 770 122	89 029 814	14 414 827	2 254 538	119 770 122	89 029 814	14 414 827	2 254 538
Amortisation charge due next year	1 273 540	13 794 515	1 273 540	264 844	1 273 540	13 794 515	1 273 540	264 844

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for the year ended December 31, 2021

		MCAZ GROUP				AUTHORITY			
		Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
		2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$
11	**Income tax expense**								
	Current tax								
	Current tax	484 081	444 329	484 081	276 428	-	-	-	-
	Deferred tax	(70 783)	(26 099)	(70 783)	(16 237)	-	-	-	-
		413 298	**418 230**	**413 298**	**260 191**	-	-	-	-
11.1	**Tax reconciliation**								
	Profit before tax	1 958 257	3 609 139	1 958 257	1 766 361	-	-	-	-
	Notional tax thereon at a rate of 24.72%	484 081	701 861	484 081	436 644	-	-	-	-
	Permanent differences	(70 783)	(283 631)	(70 783)	(176 453)	-	-	-	-
		413 298	**418 230**	**413 298**	**260 191**	-	-	-	-
11.2	**Current tax**								
	Balance as at 1 January	(59 700)	62 896	(59 700)	39 130	-	-	-	-
	Current year charge	484 081	444 329	484 081	276 428	-	-	-	-
	Payments	(499 918)	(603 187)	(499 918)	(375 258)	-	-	-	-
	Balance as at 31 December	**(75 537)**	**(95 962)**	**(75 537)**	**(59 700)**	-	-	-	-
11.3	**Deferred tax**								
	Balance at 1 January	7 217 298	3 493	7 217 298	2 173	-	-	-	-
	Deferred tax recognised through profit and loss	(70 783)	(26 099)	(70 783)	(16 237)	-	-	-	-
	Deferred tax recognised through other comprehensive income	1 366 989	3 093 101	1 366 989	1 924 294	-	-	-	-
	Deferred tax recognised directly in equity	5 646 848	8 530 556	5 646 848	5 307 068	-	-	-	-
	Net deferred tax liability	**14 160 352**	**11 601 051**	**14 160 352**	**7 217 298**	-	-	-	-
12	**Trade and other payables**								
	Trade payables	18 965 859	1 352 183	18 965 859	841 226	18 965 859	1 352 183	18 965 859	841 226
	Sundry payables	19 622 884	38 234 337	19 622 884	23 786 516	19 622 884	38 234 337	19 622 884	23 786 516
	Other Payables	72 861 984	67 542 585	72 861 984	42 019 892	72 856 551	67 534 689	72 856 551	42 014 981
	Unallocated income	3 921 281	5 552 966	3 921 281	3 454 636	3 921 281	5 552 966	3 921 281	3 454 636
		115 372 008	**112 682 071**	**115 372 008**	**70 102 270**	**115 366 575**	**112 674 175**	**115 366 575**	**70 097 359**
13	**Provisions**								
	Leave pay provision	3 854 001	1 128 022	3 854 001	701 770	3 854 001	1 128 022	3 854 001	701 770
14	**Medicines control income**								
	Amendment fees	17 562 966	16 168 445	13 594 249	6 820 171	17 562 966	16 168 445	13 594 249	6 820 171
	Clinical trials	4 103 620	5 448 939	3 417 566	1 928 089	4 103 620	5 448 939	3 417 566	1 928 089
	Dangerous drugs license	55 747 006	39 997 166	42 967 825	21 280 070	55 747 006	39 997 166	42 967 825	21 280 070
	Drug registration and forensic examination	372 237	66 115	304 733	21 200	372 237	66 115	304 733	21 200
	Import and export licenses	67 753 410	24 425 962	53 646 003	10 996 441	67 753 410	24 425 962	53 646 003	10 996 441
	Inspection	47 148 160	38 434 390	37 328 971	15 391 202	47 148 160	38 434 390	37 328 971	15 391 202
	Persons and premises licenses	25 473 753	4 589 091	19 753 083	1 436 349	25 473 753	4 589 091	19 753 083	1 436 349
	Registration fees	76 309 379	65 930 321	62 394 335	28 833 127	76 309 379	65 930 321	62 394 335	28 833 127
	Renewal of licenses	39 447 382	18 282 316	28 455 919	3 611 120	39 447 382	18 282 316	28 455 919	3 611 120
	Retention fees	103 545 773	95 693 810	81 056 732	41 968 696	103 545 773	95 693 810	81 056 732	41 968 696
	Sales representatives and wholesale dealers	6 219 019	1 420 402	4 850 491	550 080	6 219 019	1 420 402	4 850 491	550 080
	Unregistered medicines	21 376 954	4 739 925	16 664 118	1 723 958	21 376 954	4 739 925	16 664 118	1 723 958
	Veterinary permits	5 681 880	1 807 934	3 940 673	479 399	5 681 880	1 807 934	3 940 673	479 399
		470 741 539	**317 004 816**	**368 374 698**	**135 039 902**	**470 741 539**	**317 004 816**	**368 374 698**	**135 039 902**
15	**Laboratory services income**								
	Condom testing	3 534 731	12 265 425	2 816 008	5 705 463	3 534 731	12 265 425	2 816 008	5 705 463
	Glove testing	3 570 016	1 455 931	3 065 882	578 243	3 570 016	1 455 931	3 065 882	578 243
	Medical devices-registration	422 385	78 830	-	49 042	422 385	78 830	-	49 042
	Samples - external clients	85 306 852	64 317 606	71 670 623	27 779 201	85 306 852	64 317 606	71 670 623	27 779 201
		92 833 984	**78 117 792**	**77 552 513**	**34 111 949**	**92 833 984**	**78 117 792**	**77 552 513**	**34 111 949**

	MCAZ GROUP				AUTHORITY			
	Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$
16 Other income								
Amortisation for the year	1 986 265	13 794 515	1 380 524	264 844	1 986 265	13 794 515	1 380 524	264 844
Decrease in provision for leave pay	-	52 253	-	-	-	52 253	-	-
Donations	10 577 843	11 818 495	9 005 505	5 891 264	10 577 843	11 818 495	9 005 505	5 891 264
Interest earned	8 935	67 591	7 440	15 326	1 367	64 667	966	13 647
Rentals	17 786 428	12 512 007	13 998 024	5 471 899	14 375 006	8 546 803	11 330 995	3 826 012
Realised gain on disposed asset	3 104 524	-	193 126	-	3 104 524	-	193 126	-
Fair value adjustment	69 552 202	-	119 790 340	56 843 860	69 552 202	-	119 790 340	56 843 860
Sundry income	4 122 887	4 185 058	5 848 472	1 716 375	4 122 887	4 185 058	5 848 472	1 716 375
Exchange gain realised	11 311 027	64 050 871	10 742 302	33 575 886	10 428 127	62 904 062	9 859 402	32 862 428
Exchange gain unrealised	84 556 007	273 869 929	84 556 007	170 381 179	84 556 007	273 869 929	84 556 007	170 381 179
Decrease in provision for credit losses	-	304 390	-	-	-	304 390	-	-
	203 006 118	**380 655 109**	**245 521 740**	**274 160 633**	**198 704 228**	**375 540 172**	**241 965 337**	**271 799 609**
17 Administration expenses								
Audit fees	2 237 760	1 260 591	1 781 379	770 000	2 093 932	1 205 547	1 680 000	750 000
Board fees	12 001 261	12 694 543	10 237 736	5 561 203	11 839 118	12 587 102	10 110 398	5 506 599
Bank charges	7 670 799	6 289 323	6 182 808	2 650 443	7 601 985	6 259 323	6 127 037	2 634 167
Communications	2 491 213	1 925 295	1 900 784	983 191	2 491 213	1 925 295	1 900 784	983 191
Consumables	2 964 335	4 543 512	2 220 910	1 486 358	2 964 335	4 543 512	2 220 910	1 486 358
Credit losses	28 708	-	28 708	-	28 708	-	28 708	-
Depreciation for the year	50 501 835	41 459 165	7 223 148	4 137 157	50 068 516	41 025 846	6 879 917	4 080 264
Fair value adjustment	-	53 573 210	-	-	-	53 573 210	-	-
General administration	25 385 509	12 849 412	16 409 213	5 524 977	25 326 947	12 483 279	16 366 588	5 297 197
Increase in provision for leave pay	2 725 979	-	3 152 231	538 090	2 725 979	-	3 152 231	538 090
Increase in provision for credit losses	20 546 938	-	20 584 773	6 193	20 546 938	-	20 584 773	6 193
Inspections	11 032 152	12 214 912	8 936 314	4 554 501	10 566 357	11 784 602	8 545 525	4 369 744
IT expenses	10 451 398	9 374 538	8 368 564	4 591 843	10 451 398	9 374 538	8 368 564	4 591 843
Legal and professional fees	4 821 129	7 152 472	3 808 499	3 600 423	4 821 129	7 152 472	3 808 499	3 600 423
Printing and stationery	5 052 772	6 708 151	4 206 031	3 193 607	5 052 772	6 708 151	4 206 031	3 193 607
Loss on disposal of property,plant and equipment	195 839	-	173 581	-	195 839	-	173 581	-
Public relations	1 708 028	2 479 473	1 419 610	1 300 065	1 708 028	2 479 473	1 419 610	1 300 065
Quality assurance costs	2 001 849	4 398 295	1 589 832	2 307 267	2 001 849	4 398 295	1 589 832	2 307 267
Rates, electricity and water	4 007 062	1 152 060	3 206 045	562 552	4 007 062	1 152 060	3 206 045	562 552
Repairs and maintenance	7 554 748	4 765 217	6 126 256	4 237 438	7 554 748	4 765 217	6 126 256	4 237 438
Security and insurance costs	5 255 426	4 803 015	4 465 991	2 043 879	5 186 322	4 719 464	4 411 753	2 009 526
Strategic planning	10 330 907	9 658 162	9 209 913	4 580 042	10 330 907	9 658 162	9 209 913	4 580 042
Subscriptions	3 117 748	1 366 154	2 380 541	341 521	3 117 748	1 366 154	2 380 541	341 521
Travelling and subsistence	1 438 725	873 832	1 080 255	82 370	1 438 725	873 832	1 080 255	82 370
Vehicle running costs	9 721 400	4 487 967	7 912 787	2 339 686	9 721 400	4 487 967	7 912 787	2 339 686
	203 243 520	**204 029 299**	**132 605 909**	**55 392 806**	**201 841 955**	**202 523 501**	**131 490 539**	**54 798 143**

		MCAZ GROUP				AUTHORITY			
		Inflation adjusted		Historical cost		Inflation adjusted		Historical cost	
		2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$	2021 ZW$	2020 ZW$
18	**Other expenses**								
	Salaries and wages	267 151 813	272 928 044	217 991 590	125 101 314	267 151 813	272 928 044	217 991 590	125 101 314
	Pension and medical aid	31 340 139	19 536 291	25 102 827	8 395 385	31 340 139	19 536 291	25 102 827	8 395 385
	Staff training expenses	2 558 993	6 244 341	2 174 570	1 333 504	2 558 993	6 244 341	2 174 570	1 333 504
	Staff welfare	5 975 104	6 363 585	4 945 448	2 365 885	5 975 104	6 363 585	4 945 448	2 365 885
		307 026 049	**305 072 261**	**250 214 435**	**137 196 088**	**307 026 049**	**305 072 261**	**250 214 435**	**137 196 088**
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	897 054	4 160 107	655 313	233 900	897 054	4 160 107	655 313	233 900
	Board members fees	11 104 207	8 534 437	9 582 423	5 327 303	10 942 064	8 426 996	9 455 085	5 272 699
		12 001 261	**12 694 544**	**10 237 736**	**5 561 203**	**11 839 118**	**12 587 103**	**10 110 398**	**5 506 599**
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	1 576 233	1 366 648	489 130	244 453	1 576 233	1 366 648	489 130	244 453
	Director-General salary	9 072 612	16 989 869	7 036 601	8 432 344	9 072 612	16 989 869	7 036 601	8 432 344
		10 648 846	**18 356 517**	**7 525 731**	**8 676 797**	**10 648 846**	**18 356 517**	**7 525 731**	**8 676 797**

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20 Going concern

The Authority reassessed its going concern in light of the COVID 19 pandemic. The Authority took into consideration existing and anticipated effects of the pandemic on the Authority's operations in its assessment of the appropriateness of the going concern basis. The assessment reviewed that the Authority is able to continue to collect revenue and will be able to sustain its operations. The Authority does not have any local or foreign debt. The COVID 19 pandemic was an event after the end of the reporting period and it did not bring any material uncertainty that cast significant doubt on the Authority's ability to continue as a going concern. Management is satisfied that the going concern basis is appropriate.

21 Subsequent events

In March 2020,the World Health Organisation declared Covid-19 a global pandemic. The scourge has negatively impacted global economies,posing economic uncertainties with varied financial implications. Management have assessed the current economic uncertainties and market volatility caused by Covid-19 and cast no doubt on the Authority's ability to continue as a going concern.

Composition of MCAZ - Departments and Core Functions

1. Evaluation and Registration Division

- Registration of human and veterinary medicines.
- Review of complementary medicines.
- Inspection of veterinary medicines general dealer.
- Publication of the drug register.

2. Pharmacovigilance and Clinical Trials (PVCT)

- 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].
- Processing of post registration safety variations and promotional material,
- Conducting pharmacovigilance activities which include, post-market surveillance of registered medicines, collecting, causality assessment, analysing benefit/risk of adverse drug reaction (ADR) reports and adverse events following immunisation (AEFI) reports.
- Drug information dissemination through publishing drug information bulletin, articles, circulars and alert notices.
- Processing retention fees for registered medicines both human products and veterinary products.
- Medicines safety reviews.
- Processing product defects and recalls related to safety aspects

3. Licensing and Enforcement

- Conducting planned, routine & new premises inspections for monthly Licensing & Advertising Committee meetings.
- Conducting Market Surveillance and product defect investigations.
- Import and export controls including consignment verification at ports of entry
- Processing applications for narcotics
- Conducting enforcement activities in liaison with other law enforcement agents and assisting with prosecution of offenders

4. Laboratories

4.1. Chemistry Division

- The laboratory is WHO-Prequalified and ISO 17025 Accredited
- Ensure quality, safety and efficacy of medicines in the nation through testing.
- Samples analysed are for purposes of
    - Registration of medicines
    - Post-market surveillance
    - Pre-distribution analysis
    - Quality checks after adverse drug reactions on the market.

4.2. Medical Devices and Microbiology Unit

- **Medical Devices:**
    - The laboratory is ISO 17025 Accredited
    - Regulation and Quality Conformity Assessment of male condoms in accordance to SI 183 of 2005
    - Regulation and Quality Conformity Assessment of medical gloves in accordance to SI 1 of 2006
    - Factory inspections (cGMP) of condom and glove manufacturing facilities.

- **Microbiology:**
  - Quality Conformity Assessment of medicines and allied substances
  - Quality Conformity Assessment of complementary medicines
  - Evaluation of vaccine Summary lot protocols
  - Evaluation of cGMP reports for the licensing and enforcement division

5. The Legal and Corporate Affairs Unit

- The Unit implements all relevant statutes.
- Conducts constant review of legislation to ensure that it suits the changing needs of the industry.
- Where gaps are identified, the unit drafts the necessary amendments to the legislation and, with the approval of the Minister of Health and Child Care, have the regulations gazetted.
- The Unit therefore deals with all correspondence for and on behalf of the Director-General as well as advising the Authority on all legal issues.
- To conduct operational research to generate information to support the ability to respond and evolve with the changing needs of the industry.

6. ICT

- Defines the ICT policies and strategies of the Authority
- Ensures the implementation of ICT policies and strategies and provides daily technical support to users of ICT infrastructure and technology within the Authority
- Also develops and maintains ICT infrastructure that can be used by the Authority's stakeholders and customers.

7. Internal Audit Unit

- The scope of internal audit work includes the review of internal control systems, risk management procedures, information systems, financial systems and governance processes.
- This also involves periodic testing of transactions, best practice reviews, special investigations, appraisals of regulatory requirements, and measures to help prevent and detect fraud.

8. Human Resources

- To provide leadership and guidance in, and have control over, all the Human Resources affairs of the Authority through policies and procedures designed to ensure that the Authority achieves its objectives.
- To facilitate strategic human resource planning at all levels and the development of appropriate activities to attract highly competent talent.
- To continuously develop and facilitate performance management methods and processes throughout the organization and communicating outcomes for further HR planning.
- To identify and facilitate relevant training and developmental opportunities in terms of the overall learning and growth strategy of the organization.
- To champion a culture that encourages and rewards individual growth.
- To facilitate the design and implementation of reward systems that maximize staff retention and contribution.
- To promote a culture of a harmonious industrial relations climate.

9. Finance

- Cash Flows - To control the cash flow position throughout the Authority to understand the sources and uses of cash, and maintain the reliability of the streams of funds for the Authority
- Accounts Receivable and Payable - The finance department also makes sure that creditors are taken care of and pay all due bills to vendors in time. And also, to ensure that debtors pay within their approved debtor days.

- Investments - The Finance department is responsible for managing the financial operations functional responsibilities.
- Accounting/Reporting – Preparing financial reports for the Authority, as well as liaising with the Office of the Auditor General in conducting annual financial audits.

10. Quality Unit

- Responsible for development & implementation of the Quality Management Systems (QMS) i.e.:
    - ISO 17025 Standard
    - ISO 9001 Standard
    - ISO 17020
    - cGMP & WHO Pre-Qualification
    - Good Laboratory Practices
- Manages the Complaints Handling System
- Customer focus
- Conducts QMS Audits and regular trainings
- Monitoring all corrective and preventive action implementation to ensure improvement
- Responsible for accreditation, certification and Pre-Qualification processes
- Responsible for organisational Samples Management
- Responsible for all global procedures and document control.
- Operational Risk monitoring-effectiveness checks

The Authority response to COVID-19 pandemic

The outbreak of the COVID-19 pandemic has transformed the way organisations are run and the working environment. To contain the spread of the COVID-19 pandemic, the government first introduced a total lockdown in March 2020. Only essential services were allowed to operate and MCAZ was classified as such. However, to decongest the office, the Authority had to introduce working from home model, virtual meetings and shifts in a bid to comply with the COVID-19 induced restrictions. The Authority after approving its Health and Safety Guidelines on Covid-19 continued to encourage its employees and stakeholders to observe and adhere to the health protocols as done in the previous year when the pandemic first emerged. Some of the protocols included automation of key customer processes, encouraging stakeholders and staff to be fully vaccinated for Covid-19, practising social distancing and wearing face masks, especially in public places. Mandatory hand sanitizing, avoiding physical/face to face meetings and instead hold virtual meetings where possible. Some meetings were hybrid with other participants attending physically while others joined virtually. The working-from-home model had some challenges as staff were adjusting to the new model for working. The Authority's ICT unit played a critical role in making sure that the organisation adapted to the "new normal" by putting in place systems that made sure the work of the Authority was not negatively impacted. The ICT unit maintained the virtual private network (VPN) which assisted MCAZ officers to work off premises while accessing internal applications. The unit also pioneered online services which allowed applications for person and premises renewals to be lodged online by clients. The ICT staff were available to assist any client remotely through their application process if they faced any challenges. This increased customer satisfaction. To make the online application process easier for our clients, the ICT Unit maintained the same familiar User Experience and User Interface that external stakeholders have continued to use since the launch of Online imports of Registered Medicines in 2020.

Human Resources

As of 31st December 2021, the Authority's headcount of approved posts was 133 i.e. 80 females (60%) and 53 males (40%). The number of approved posts stood at 155 and 133 were filled (86%) leaving a vacancy rate of 14% i.e. 22 posts. Out of the 22 approved Managerial positions, 15 were filled i.e. 8 females (53%) and 7 males (47%). There were also four (4) project-funded posts filled as of 31st December 2021.

In the same period under review, the under-listed HR policies were developed to ensure continued compliance to best practice:

- Whistleblowing
- Honorarium
- MCAZ Committee Members' Tenure of Office.

Focus on notable changes and developments

The most notable changes and developments within the business was a paradigm shift brought about by the Covid-19 pandemic. It led to the accelerated emergence of flexible and remote working models. This obviously had some impact on the employment relationships whereby in some cases there was some marked increase in resignations, limited learning and development initiatives, low employee engagement among others. However, there were also some positives such as accelerated automation of key processes, more focus on good governance and sustainable business strategies among others.

Capacity development issues undertaken

In 2021 there were significant training and development programmes undertaken by staff that included online and on-the-job training courses. In total, 73 key training programmes were undertaken and such investment contributed to the achievement of the desired objectives of the business as well as employee satisfaction and morale. Unfortunately, some planned external face to face programmes could not be undertaken due to the continued risks of the COVID-19 pandemic.

Key/notable achievements

Despite the challenges brought about by the global covid-19 pandemic, the Authority managed to play its instrumental role in securing the present and future success of its mandate through the Human Resources Committee in so far as the HR functions were concerned. Its major function was guided by its long-term vision of working in partnership to create an environment where employees could thrive and were enabled to deliver sustainable organizational performance. Some of the achievements included the under-listed:

- Holding all scheduled Committee meetings
- Continuous minimization of Covid-19 risks through regular education, communication, information strategies.
- Payment of monthly salaries and allowances to staff
- Upward review of employee remuneration, where sustainable
- Implementation of appropriate and relevant learning and development programmes for staff.
- Maintaining a harmonious industrial relations climate
- Fostering a high-performance culture amongst employees and the business.

Lessons learnt and plans for the future

One of the biggest and most significant lessons learnt especially as a result of the emergence of the covid-19 pandemic was to foster long-term resilience of both businesses and human capital and prepare people to manage instant changes in a volatile, uncertain and complicated work world of today.

Evaluation and Registration

Registration of human medicines

The Evaluations and Registrations (EVR) Division assesses applications for medicinal products. The EVR Division reviews safety, quality and efficacy of medicines intended for marketing, sale and distribution in Zimbabwe in accordance with the requirements of MASCA [15:03], MASCR SI 150 of 1991, the MCAZ Registration Guidelines, Registration Committee policies and approved internal procedures (SOPs) which are in accordance with the MCAZ Quality Management System (QMS). EVR comprises the Human Allopathic Medicine, Complementary Medicine and Veterinary Medicine Units responsible for assessment and registration of human, complementary and veterinary medicines including post-registration variations.

Key/notable achievements

The Division exceeded its 2021 human medicines revenue target by about 31.6% from pre-registration applications and by about 21.5% from post-registration applications

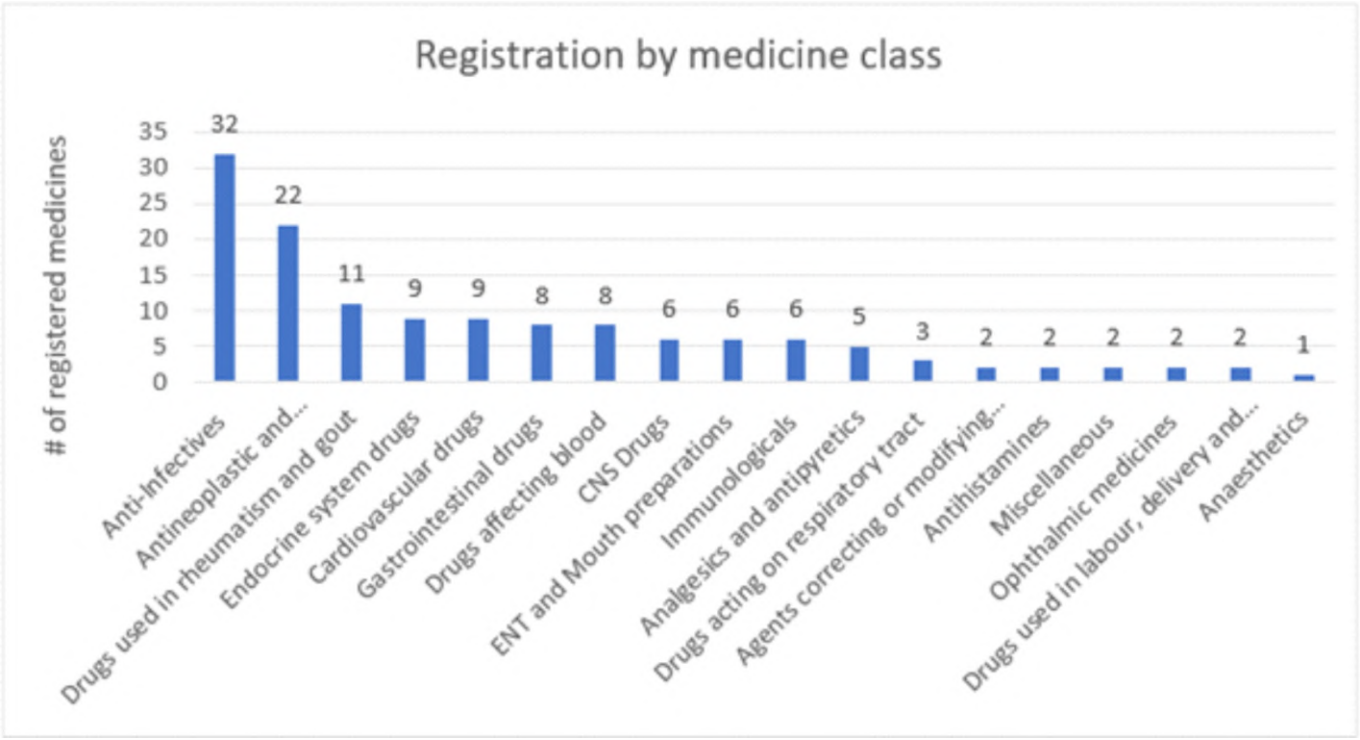
Table 3 Key Notable achievements

Month	Registered	Refused	Withdrawn
January	16	0	2
February	16	11	0
March	9	0	0
April	7	0	0
May	15	4	0
June	8	0	0
July	15	0	0
August	11	21	1
September	12	1	0
October	19	1	1
November	8	2	0
December	11	1	0
Total	**147**	**41**	**4**

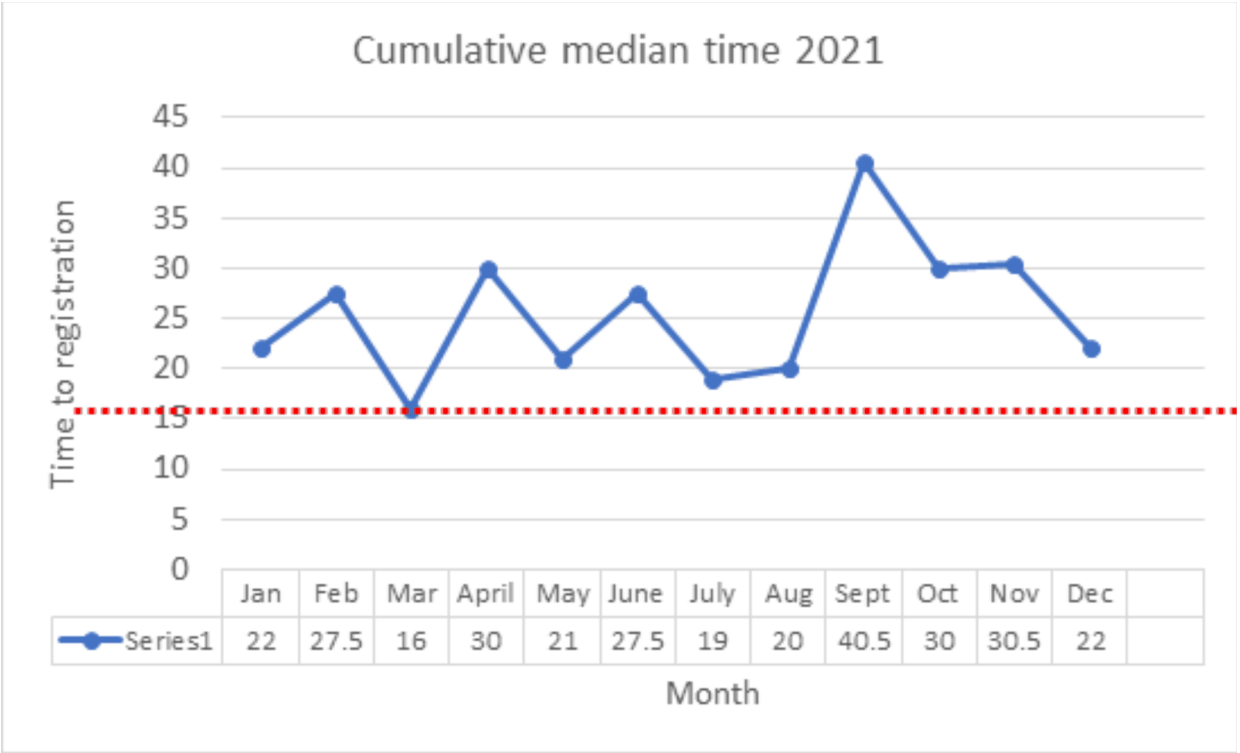
There was a 37% increase in new registrations compared to the same period last year.

Graph 1 Registered products by pharmacological class

Below is a summary of the pharmacological classification of the products registered in 2021:.



Graph 2 Cumulative median time to registration for 2021



The cumulative median time to registration for 2021 was 24.75 months (16 – 40.5 months) against a target of 16 months. This is inclusive of the manufacturers' time to respond to queries.

Lessons learnt and plans for the future
Going forward, the unit will continue with the upgrading and replenishing of ICT online platforms and infrastructure. This will be key to the Division's performance, as it supports the working from home model adopted by the division and also increase client authority interactions.

Zazibona Activities

The Division continues to be engaged in regional assessment activities. In 2021, the Division assessed 14 of the 26 applications for registration which were discussed under the Zazibona collaboration. In addition, the Division assessed 12 of the 30 responses/additional information packages discussing the Zazibona collaboration. The coordination of the assessments continue to be carried out by assessors in the Division which has resulted in the organisation having recognition across the region.

Registration of veterinary medicines

The Veterinary Unit complies with the provisions of the Medicines and Allied Substances Control Act (MASCA) [15:03] and the MCAZ guidelines in handling applications for registration, amendments, and clinical trials of all animal medicines. The process incorporates principles of the World Organisation for Animal Health (WOAH) and Southern African Development Community (SADC). In 2021, MCAZ was appointed to the Dipping Committee of the Department of Veterinary Services in order to jointly assess the applications for dipping trials facilitating quicker reviews and timely feedback to industry. Jointly the two institutions will review dipping trial guidelines and facilitate a regulatory environment conducive for supporting local industry to manufacture acaricides that will protect livestock against tick borne diseases such as Theileriosis, commonly known as January disease which occurs in cattle.

Regionally, the unit continued collaborating with the Veterinary Zazibona countries, comprising Botswana, Malawi, Namibia, South Africa, Tanzania, Zambia and Zimbabwe. The initiative was established to jointly assess veterinary medicinal products and it is currently supported by the Bill and Melinda Gates Foundation and facilitated by the United Kingdom Veterinary Medicines Directorate. This initiative was able to agree on common application forms and develop common guidelines for registration of veterinary medicines in the SADC region. Chaired by MCAZ, the initiative plans to invite applications for registration of veterinary medicines from industry that will be jointly assessed in 2022. It is envisioned that this regional collaboration will establish capacity building in the region and promote registration of safe, quality and efficacious veterinary medicines.

Key/notable achievements

Approval of veterinary medicines
Achievement: The unit surpassed its total revenue target by 23%. This was attributed to the increase in submissions for applications for post-registration variations. A total of twelve (12) applications for registration were registered against twenty-four (24) new applications for registration that were received. Sixty-nine (69) post-approval applications were received and sixty-seven (67) of these were reviewed. Four applications for clinical trials were submitted and authorised in 2021.

Business Continuity under lock down
Achievement: The Unit continued business operation observing strict Covid-19 regulations. Staff conducted most of its business operations virtually and this included client meetings and Committee meetings.

Lessons learnt and plans for the future

The Unit anticipates boosting the number of pre-registration and post-registration applications through the SADC Veterinary Medicinal Zazibona harmonisation initiative in 2022. The initiative will also result in submission of innovative products to the country offering wider alternatives to animal health products to farmers.

Approval of complementary medicines

The Complementary Medicines Unit is responsible for approving complementary medicines. Complementary medicines are medicines which are used in mitigation or prevention of diseases or abnormal physical, mental state or symptoms in humans or animals, restoring, correcting or modifying any physical, mental or organic function in man or animals, which originate from plants, minerals, animals and insects. These include: herbal, probiotics, nutraceutical, homeopathic medicinal products used as adjunct to treatment with allopathic medicines. They are approved under the Complementary Medicine Regulations, SI 97 of 2015.

The Complementary Medicines Team comprises two regulatory officers supervised by a Senior Regulatory Officer. Current timelines to first evaluate an application is 2 months and the overall time to register lies between 6 to 12 months. The Complementary Medicines Unit reports to the Complementary Medicines Sub-Committee once in every 2 months.

Key/notable achievements

The following goals were attained in the year 2021:

i. **Approval of complementary medicines**

Achievement: In 2021, fifty-five (55) applications for complementary medicines were approved bringing the total of approved products to 295. This is a 30.95% increase as compared to the previous year. No applications were refused. An 81.82% decrease in the number of applications withdrawn was noted as two (2) applications were withdrawn in 2021 compared to eleven (11) applications in 2020.

A 115.56% increase in the number of applications received was noted in 2021 as compared to 2020. Ninety-seven (97) applications were received in 2021 whereas forty-five (45) applications were received in 2020.

ii. **Stakeholder Consultation**

Achievement: The Division continued to engage stakeholders via virtual and physical meetings. These meetings led to the submission of applications and some of the meetings were facilitative e.g the Division engaged with the National Biotechnology Authority on issues related to the application of Cosol.

iii. **Response to the COVID-19 pandemic**

Achievement: The Authority managed to approve some therapeutics targeted for Covid-19 related ailments. This includes among others, the local product Cofsol manufactured by the National Biotechnology Authority.

Lessons Learnt

Due to the increase in the number of applications for the registration of complementary medicines, the Unit plans to conduct trainings and /or consultative meetings on how to present information for the application of complementary medicines and the documentation required so as to shorten the registration timelines by reducing number of cycles between MCAZ and the applicant.

The unit also plans to send staff for more training and placements offered by other National Regulatory Authorities with regards to assessment of complementary medicines, to improve their assessing skills.

It was also noted that a few applications received in 2020 and 2021 required use of the reliance approach during assessments. The unit therefore plans to document a Reliance approach policy that will facilitate use of reliance in a consistent manner.

Pharmacovigilance and Clinical Trials

MCAZ is the National Centre for Pharmacovigilance and is an official member of the WHO Programme for International Drug Monitoring from 1998 to date. The mandate for the MCAZ as a national pharmacovigilance/vigilance centre is in line with sections 29 (1) (a) and (b) and section 33 (3) of the Medicines and Allied Substances Control Act [Chapter 15:03] legislation and Level 3 WHO Global Benchmarking Tool (GBMT). The national pharmacovigilance centre has conducted several active and enhanced pharmacovigilance programs annually to integrate pharmacovigilance into public and private health programs. As a result the reporting of Individual Case Safety Reports (ICSRs) (ADRs, SAEs & AEFIs) has increased to over five thousand (5000) as of end of 2021. Benefit-Risk assessment and risk minimisation including causality assessment, signal assessment and communication is done routinely by the Pharmacovigilance Clinical Trials (PVCT) Committee and secretariat.

The MCAZ identifies suspected safety signals of medicines and vaccines such as serious reactions, unknown or poorly characterized adverse reactions and communicates the information in a way that improves therapeutics and promotes patient safety. Furthermore, the PVCT Division identifies quality problems in medicines resulting in ADRs. The MCAZ applies information from pharmacovigilance for the benefit of public health programs, individual patients, national medicines policies, and treatment guidelines. All ICSRs received by MCAZ are uploaded in an anonymous format onto the e-PV system for causality assessment evaluation by the monthly PVCT Committee and WHO drug safety database known as VigiBase for further signal detection in comparison with anonymous global safety data. In 2021 the MCAZ conducted a haemovigilance stakeholders meeting for the proposed haemovigilance draft regulations in consultation with the Minister for Health and Child Care and National Blood Services of Zimbabwe (NBSZ).

Table 4: Individual Case Safety Reports (ICSRs) (ADRs, AEFIs & SAEs) Reports received in 2021 are highlighted in the table below.

Type of ICSR reports	Number received and processed	Percentage of total ICSRs	Comments
ADRs and SAEs received from pharmaceutical Industry	57	7%	ADRs and SAEs are received from the pharmaceutical industry as and when they occur. There was a small increase in the number of ICSR received from the pharmaceutical industry in 2021 (57) as compared to 2020 (40).
Adverse Events Following Immunization (AEFIs)	445	53%	There was a tremendous rise in the number of AEFI reports received in 2021(445) as compared to 2020 whereby 51 reports where received. This is mainly attributed to the COVID-19 vaccination program which occurred in 2021. Healthcare practitioners were also trained in AEFI reporting in 2021 and also the stimulated reporting through the STARSS project contributed to the high number of reports received. Among the 445 AEFI reports received in 2021, 134 reports were received from the routine child vaccinations and 311 were from the COVID-19 vaccinations. 101 reports were serious and 344 were non serious. Causality assessment was done for all AEFI reports and feedback was provided for all the reports received and processed.

ADRs from the TSR of all essential medicines including ARVs and Anti- TBs from public MoHCC sites and some private sector clinics and doctors	235	28%	There was a decrease in the number of ADR reports received in 2021 (235) as compared to 2020 (473). This could be attributed to the fact that Healthcare professionals were more focused on reporting of adverse reactions associated with the new COVD-19 vaccinations. Furthermore due to the COVID-19 disease less pharmacovigilance training were conducted in 2021. Of the 235 reports received 126 of the reports were associated with ARVs drugs, 96 reports with anti-TBs drugs and 13 reports with other essential medicines ADRs from the TSR of all essential medicines are reported as and when they occur. These reports tend to increase if there are provincial pharmacovigilance training programs done.
SAEs from approved Clinical Trials conducted in Zimbabwe	109	12%	These are Serious Adverse Events (SAEs) from approved clinical studies and are reported as and when they occur. These are closely monitored as it is a mandate for principal investigators to report the SAEs.
Totals	**846**	**100%**	There was a 6% increase in the number of total ICRS received in 2021(846) as compared to the year 2020 where 801 reports were received.

Feedback was provided to the health care practitioners through written letters, presentations at the pharmacovigilance workshops and through the medicines bulletins available on the MCAZ website.

The graph above shows the distribution of ADR and AEFI reports by province in 2020 versus in 2021.

Pharmacovigilance Trainings

In 2021, the MCAZ in partnership with the Clinton Health Access Initiative (CHAI) and the Ministry of Health and Child Care (MoHCC) conducted physical on-site pharmacovigilance training in all the ten provinces of Zimbabwe. A total of 24 sites were visited and 414 health care professionals were trained. The aim of the pharmacovigilance trainings is to promote patient safety by training health care professionals to continuously prevent, minimise, successfully identify, manage and report serious adverse reactions including monitoring and evaluation. Health care professionals were also trained on how to report ICSRs (ADRs & SAEs) using the e-PV reporting system available on hyperlink https://e-pv.mcaz.co.zw. Pharmacovigilance materials including ADR reporting forms were also distributed to the sites and collection of completed forms.

Following the introduction of the COVID-19 vaccination programme in Zimbabwe in February 2021, Adverse Events Following Immunisations (AEFI) surveillance refresher trainings were conducted in February and April 2021 and M&E on 13th to 24th of September 2021 for all the provinces in Zimbabwe. The trainings were conducted in conjunction with the MoHCC-Expanded Programme on Immunization and MCAZ. The aim of the training was to equip healthcare professionals involved in vaccinations with the knowledge on how to detect, manage, report and investigate AEFIs associated with COVID-19 vaccines and other vaccines. This training program also involved a major component of monitoring and evaluation whereby more than 200 AEFIs were collected from the sites and distribution of AEFI forms. These trainings subsequently led to an increased number of AEFI reports that were received by the MCAZ. The challenges noted were that more capacity building is required at vaccination clinics for serious AEFI case management, expedited reporting of AEFIs and need for more post-mortem facilities at district level to enable casualty assessment by the national AEFI Committee that is also the PVCT Committee.

Electronic ADR reporting and Electronic Clinical Trials application and registry system

In 2018, the MCAZ through its implementation partners IntelliSOFT Consulting Group based in Kenya and with funding from Global Fund HIV grant through UNDP successfully developed an e-ADR reporting and e-Clinical Trials (CT) application and registry system. The e-systems were expected to increase efficiency and ease of doing business by both the internal staff and customers. The electronic Adverse Drug Reaction (e-ADR) reporting system allows for web based, mobile phone reporting and desktop offline reporting. The e-ADR reporting and e-Clinical systems were launched in 2019. In 2020 and 2021 the systems were fully functional and 26 e-ADR reports were received in 2021 as compared to 20 received in 2020. Hence more resources such as health information officers, high speed internet and training of the cadres to be able to use the effort is needed to disseminate the e-ADR system and also to capacitate healthcare professionals in order for them to increase e-ADR reporting. All the other ADR reports that were received in 2021 as paper based forms were entered into the e-ADR system and processed through the system. Following the circular sent to researchers in 2019 communicating that clinical trials applications were required to be submitted through the e-CTR electronic application system, researchers started to submit the applications online and all the nine (9) clinical trial applications received in 2021 were submitted and processed online. This improved the quality and completeness of the clinical trial applications received. The efficiency of processing clinical trials was also greatly improved. These were notable achievements in line with the Authority's strategy for automation of its processes and key result areas for effective automated systems.

Projects

In 2021 the division undertook several projects as highlighted below;

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 m-health - new way to collect information about adverse events that sometimes occur after vaccination. This m-health 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 with three wards participating in the enrolment of participants i.e. Post Natal Ward, Caesarian section Ward and OPD Vaccination clinic. Activation for CITIMED Private Hospital was done on the 7th of November 2020 with the Post Natal Ward and Vaccination Clinic taking part in the enrolment of participants. A total of 4,500 participants including children and/or adult/healthcare worker vaccine recipients were recruited. Children 0 ≤5 years vaccinated at the 2 sites and adult/healthcare workers who got the COVID-19 vaccines at the 2 sites were recruited. The study reached the target enrolment on the 24th of May 2021 and enrolment was stopped. By the end of 2021 data analysis was being done for the data collected and the results of the study would be published in due course.

Increasing the regulatory capacities for review of clinical trials in Southern Africa by establishing European-African collaborations that facilitates implementation of efficient processes, harmonised procedures, standardized guidelines, and effective training programme. (SEARCH Project)

The project is funded by the EDCTP and is being coordinated by the Manhica Health Research Center of Mozambique with the MCAZ acting as the consultants for the project. The overall aim of the project is to provide capacity building for the three countries Botswana, Eswatini and Lesotho in clinical trials review, approval, and oversight. The project is divided into three phases. The objective of phase 1 and phase 2 was to conduct a situational analysis for the three countries to identify the strengths, weaknesses and gaps which need to be addressed and to provide recommendations for the way forward. The objective of phase 3 is to build capacity for the three countries in line with the gaps identified in phase 1 and 2. Phase 1 and 2 activities for the three countries were conducted in October to December 2021 by the Lesotho Ministry of Health (MoH) National Medicines Regulatory Department (NMRD) team, Botswana Medicines Regulatory Authority (BoMRA), Eswatini National Regulatory Authority (NRA) team and the MCAZ consultants. The assessments were done using the WHO Global Benchmarking Tool (GBT) self-assessment tool. Supporting documents such as legislation, guidelines, standard operating procedures were used for the evaluation process. Gaps for each country in clinical trial oversight were identified and plans on how to address these gaps were agreed to.

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

The project is funded by 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 May 2021 a SPaRCS public webinar and launch event was held whereby a range of stakeholders attended. This event was attended by more than 90 participants from numerous African countries and served as the SPaRCS project launch, as due to COVID-19 restrictions it was not possible to have a formal, in person project launch at the beginning of the project as envisaged. Ethical approvals were secured in all countries and institutions including Zimbabwe.

Three virtual interactive workshops were held in October and November. 2021. The workshops covered the following areas.

- Advocacy and communication of pharmacovigilance
- Patient/consumer ADR reporting plus E-reporting of ADRs
- Using country level Pharmacovigilance data to make regulatory decisions

The MCAZ through the PVCT division participated in all the training workshops.

2021 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 2021 the division managed to conduct four (4) RCORE trainings highlighted in the table below.

Table 5 2021 RCORE Trainings

Country	Institution(s) Trained	Name of Course	Training Dates
Gambia, Liberia and Sierra Leone	Medicines Control Agency of Gambia, Liberia Medicines and Health Products Regulatory Authority and Pharmacy Board of Sierra Leone	Pharmacovigilance Regulatory Systems Strengthening	1-5 March 2021
Gambia, Liberia and Sierra Leone	Medicines Control Agency of Gambia, Liberia Medicines and Health Products Regulatory Authority and Pharmacy Board of Sierra Leone	Clinical Trials Regulation Oversight and Reliance	3-6 May 2021
Uganda	National Drug Authority of Uganda	Training on Assessment of Clinical Trial Applications and Good Clinical Trial Practice	19-21 July 2021
Namibia	Namibia Medicines Regulatory Council(NMRC)	Pharmacovigilance and Clinical Trials Training	20-24 September 2021

Publications

Medicine Information Bulletin

To disseminate medicine information, the PVCT division managed to publish a medicine information bulletin in July 2021. The bulletin was distributed through various channels to all the relevant stakeholders. The bulletin covered the following topics

- COVID-19 Vaccines, updates and frequently asked questions
- Ivermectin for COVID-19
- Medication Errors
- Substandard and Falsified Medicines
- Pharmacovigilance regulatory safety updates
- Medicines safety alerts
- STARSS Project
- Safety review of undesirable ingredients
- RCORE activities
- Electronic ADR Reporting

WHO Level 3 Global Benchmarking Tool Assessment held in August 2021

The MCAZ was formally assessed by the WHO from the 16th to the 27th August of 2021, using the WHO Global Benchmarking Tool (GBT) , for all its functions including the Clinical Trial Oversight and Vigilance Functions. Maturity Level 3 is the desired level for fully functional national medicines regulatory agent. Maturity Level 3 was successfully obtained for the Clinical Trial Oversight Regulation Function which implies that there is a stable, well-functioning and integrated regulatory system for clinical trial oversight Please see result in figure 1 below. Maturity level 1 was obtained for the Vigilance function and gaps identified were mainly due to legal provisions for vigilance activities which were since addressed using section 29 provisions of MASCA Chapter 15:03. The next follow up WHO GBT will be a physical assessment to be conducted in 2022.

Figure 1 MCAZ awarded WHO GBT Clinical Trial Oversight Maturity Level 3 on 26 August 2021

Guidelines

The following guidelines were developed and approved in 2021

- Pharmacovigilance guideline for pharmaceutical industry : Rev 0 March 2021
- Guidelines for conducting Good Clinical Trial Inspections in Zimbabwe: Rev 0 May 2021
- Guideline for Pharmacovigilance of COVID-19 Vaccine AEFI Safety surveillance: Rev 0 May 2021

The guidelines were uploaded on the MCAZ website and disseminated to various stakeholders

Human resources capacity development 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 2021 in line with the training plan to develop their capacity. Most of the trainings were conducted virtually in response to the COVID-19 pandemic.

Table 6 Human resources capacity development undertaken

Program/Course	Date	Venue	Number of Officers Trained
Good Clinical Practice Training	12-14 August 2021 and 22 November 2021	Virtual	6
NEPAD Agency RCORE in Clinical Trials Oversight	23 September	Virtual	8
Clinical Assessor Talent Building within African Regulatory Agencies Training on Clinical Evaluation -BMGF	28 July – 17 November	Virtual	4
WHO - National AEFI Committees Training on COVID-19 Vaccines Causality Assessment	25 February 2021	Virtual	7
Uppsala Monitoring Centre (UMC): Entering Adverse Events Following Immunisation (AEFI) Reports in Vigiflow	14 January 2021	Virtual	2
Signal detection disproportionate analysis: Training part 2	30 June	Virtual	10
PharmaReg Africa Summit Pharmacovigilance training	16&17 September 2021	Virtual	10
Signal detection VigiPoint and disproportionate analysis IC025 training	21 September 2021	Virtual	3
UMC Course: Introduction to Pharmacovigilance	15-30 September 2021	Virtual	3
UMC Course: Communicating the importance of PV	20-29 September 2021	Virtual	2
UMC Course: Collecting High Quality ADR Reports	24 September-12 October 2021	Virtual	2
Introduction to signal detection	October 2021	Virtual	4
Introduction to Pharmacovigilance	October 2021	Virtual	4
Signal assessment	October 2021	Virtual	4
Statistical Reasoning and Algorithms	October 2021	Virtual	4
Causality assessment of Single Case Safety Reports	October 2021	Virtual	4
Causality Assessment of Case Series	October 2021	Virtual	4

POST REGISTRATION ACTIVITIES

Safety variations and reports

Post registration applications such as safety variations, re-categorisations 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 7 Safety variations and reports

Category	Applications received	Applications processed	Timeline for processing (months)	Actual time taken(months)
Package insert updates	48	48	2	2
Additional Indications	6	6	2	2
Periodic Safety Update Reports	8	8	2	2
Re-categorizations	1	1	3	3
Promotional materials	24	24	2	2
Safety Signals	1	1	2	2
Totals	**88**	**88**		

Changes in Category of Distribution for Medicines based on ingredients

The Authority received one application for re-categorisation in 2021. After review and consultation the following change in category for distribution was approved by the Authority;

i. Desogestrel/ ethinyl estradiol 150mcg/30mcg Tablets and other similar hormonal preparations from Prescription Preparations (P.P.) to Pharmacist Initiated Medicines (P.I.M.).

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 2021 in line with the key result area number 1, Sustainable Resources Base.

Table 8 Annual retention of registered medicines

Category	Annual Target (USD)	Amount Received (USD)	Percentage of the Annual Target
Allopathic foreign medicines	US$790 000	US$ 717,275.00	91%
Allopathic local medicines	ZWL equivalent of US$58 000	USD$ 70,958.38	122%
Complementary medicines	US$15 000	USD$21,869.50	146%

As highlighted above 91 % of the expected target was reached for retention fees of products which are manufactured externally. This might have been due to the negative effects of COVID-19 pandemic experienced by the foreign applicants. However annually at least 5% product registrations are voluntarily cancelled by the applicants by not paying retention fees and 90-95% of the target amount is usually collected annually. The local applicants performed very well in payment of 2021 retention fees and the amount collected exceeded the target. This might have been attributed to more product registrations by the local applicants and also that in 2021 there was no local company which submitted payment plan proposals to the Authority. All the local applicants paid their fees in full. Retention fees for complementary medicines also exceeded the target as shown in the table above.

CLINICAL TRIALS ACTIVITIES

Applications must be made for authorisation of clinical trials of medicines in humans, including applications for amendments to the protocol, serious adverse event (SAEs) reporting, progress reports and good clinical practice (GCP) inspections and applications for importation of investigational products. Nine (9) clinical trial applications were received in 2021. There was a decrease in the number of applications received in 2021 as compared to 2020 whereby 15 applications were received. This could have been as a result of the impact of the COVID-19 pandemic. However, on average around 9 to 10 clinical trials have been received over the years. All the clinical trials received in 2021, were received through the e-CTR system and processed within timelines using the same system. Of the 9 clinical trials received in 2021, 3 were phase 1/2 studies, 5 were phase 3 studies and one was an observational study. 5 clinical trials received were for HIV prevention and management and 3 were for COVID-19 disease and one application was for maternal care. The applications received for COVID-19 disease were processed using the expedited review process since COVID-19 was declared a public emergency.

All the applications received were processed within the target timelines of 60 day working days and 15 working days for the expedited review applications. A total of 36200 USD was generated from clinical trials against an annual target of 32 000 USD. Due to covid-19 restrictions virtual GCP inspections were launched in 2021. 3 virtual GCP inspections were subsequently conducted against an annual target of four. More GCPs inspections could not take place due to the COVID-19 pandemic restrictions. Compliance with GCP is also monitored through active MASCA Chapter 15:03 mandatory monitoring from start to finish of the study adverse effects reporting requirements, monthly causality assessments of ADRs & SAEs, processing of amendments to clinical trial protocols, clarification memos, protocol deviation reports, progress reports and review of data safety monitoring board reports. The table below shows various reports which were received and processed in 2021.

Table 9 Clinical trials activities

Type of report	Number of Reports Received	Number of reports processed
Protocol Amendments	70	70
Safety reports/Updates	56	56
DSMB reports, Progress reports and Final reports,	124	124
Applications for importation of investigational products	182	182
Protocol Deviations	226	226

All the monitoring reports were processed within timelines.

Lessons learnt and plans for the future

Lessons

- Staff need to have adequate IT infrastructure such as internet and laptops
- Need to increase automation of all the process e. g. for processing retentions fees
- More output was observed from the Work from Home concept with officers recording daily work logs
- Need for change of supervision methods since officers won't be in office all the time some will be working from home.
- Virtual meetings were feasible and could be conducted smoothly and improved discussions and shortened times for meetings e.g. Committee meetings

Plans for the future

- Full automation of retention fees processing.
- Although MCAZ deployed 100 % automated ADRs/SAEs /AEFIs reporting systems and Clinical Trials applications via mobile applications, laptops, and desktop offline applications, there is need for researchers, private and public health reporters (MoHCC) to also assist in building in-house online reporting systems i.e. e-health
- Automation of applications recording and tracking systems.

Licencing and Enforcement

In 2021, 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

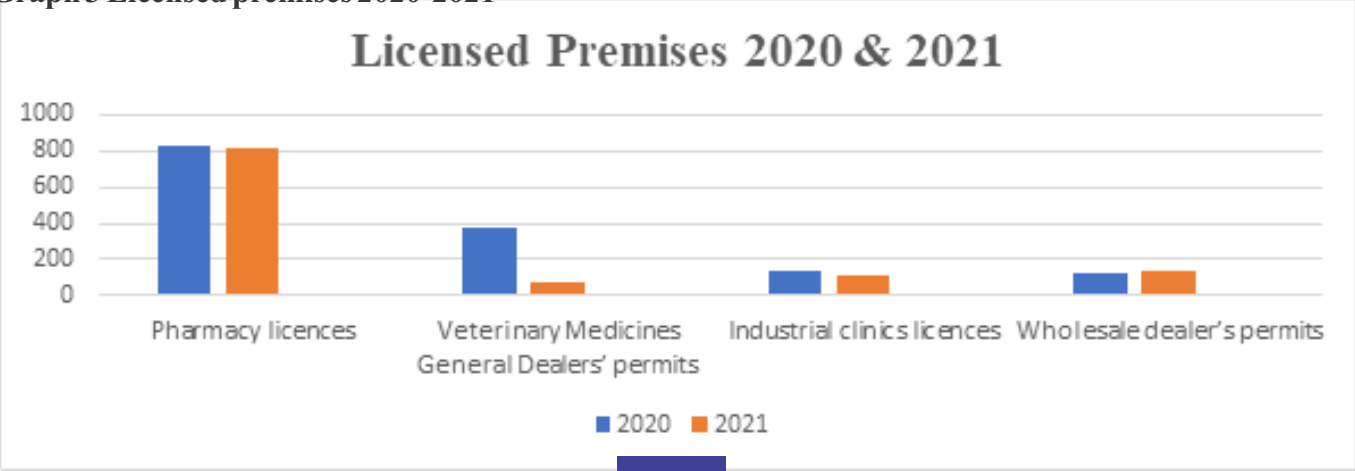
Licensing

Table 10 Licensing of premises

Licenses and Permits	2020	2021
Pharmacy licences	828	815
Veterinary Medicines General Dealers' permits	380	70
Industrial clinics licences	134	111
Wholesale dealer's permits	120	134
Medical practitioner's dispensing licences	34	45
Manufacturer's licences	11	13

2021 witnessed a decline in applications for pharmacy licences, veterinary medicines general dealers permits and industrial clinic licences. The decrease can be attributed to the increase in Covid-19 cases and consequent travel restrictions. However, 2021 witnessed an increase in applications for wholesale dealers permits and manufacturers. The increase was attributed to an increased demand for medicines due to Covid-19 related illnesses and the facilitative regulatory initiative aimed at promoting local production. This resulted in two (2) more local manufacturers being licensed in 2021.

Graph 3 Licensed premises 2020-2021



2021 marked a 22.2% increase in the number of Section 75 applications received and processed for institutions. There was however no significant change on applications processed for individual prescriptions. The relative importation of unregistered products can be attributed to the implementation of Circular 4 of 2019 which allowed institutions to import medicines in bulk through parallel importation.

Table 11 Authorisation for importation of unregistered medicines

Section 75	2020	2021
Institutions	939	1148
Prescriptions	1088	1067
Donations	113	56

Graph 4 Authorisation for importation of unregistered medicines

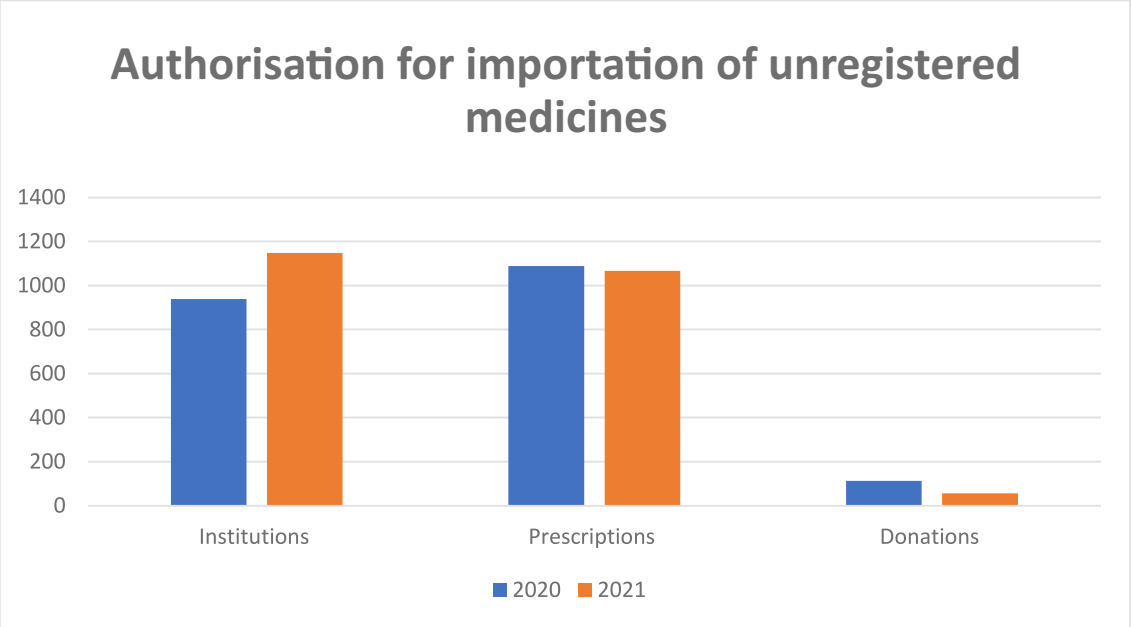
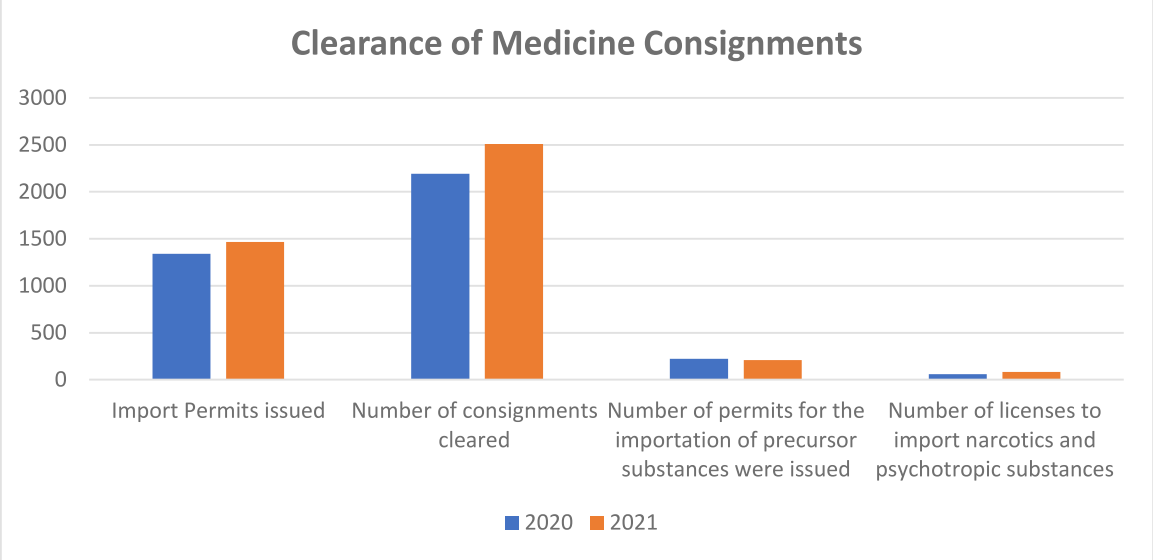


Table 12 Clearance of medicine consignments

Administrative issues	2020	2021
Import Permits issued	1340	1465
Number of consignments cleared	2194	2509
Number of permits for the importation of precursor substances were issued	221	210
Number of licenses to import narcotics and psychotropic substances	57	84
Export permits issued	94	117
Number of licences to possess, acquire and administer narcotics, including game capture licences	14	1

Graph 5 Clearance of medicines consignments



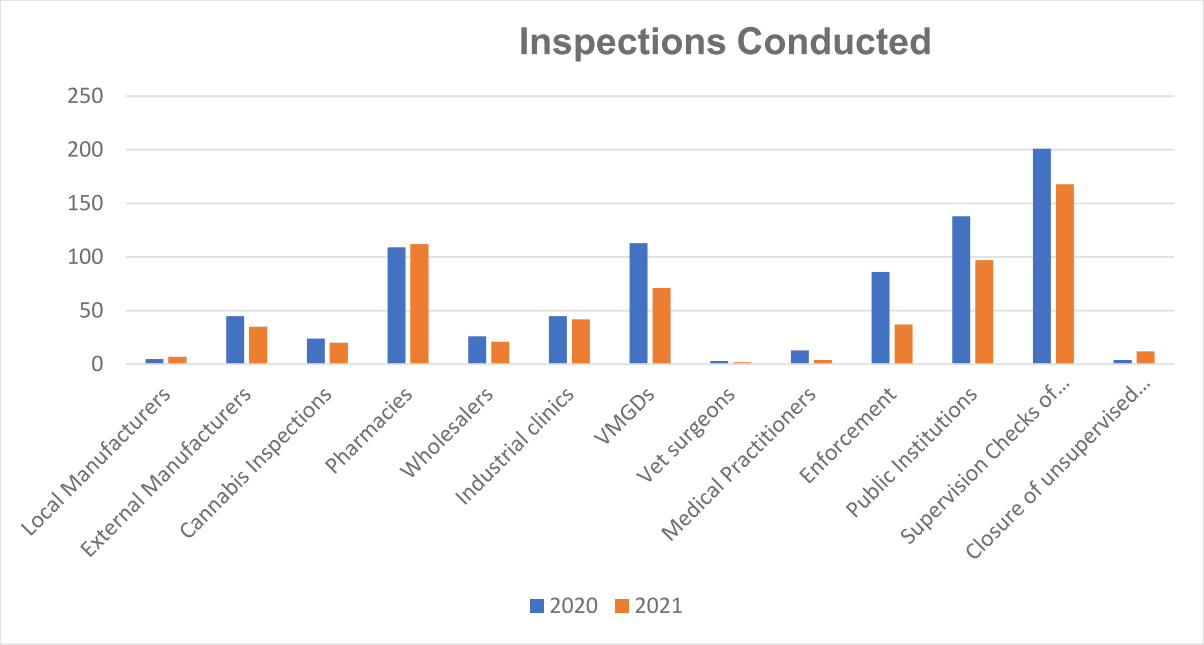
There was generally a normal distribution for all the administrative activities processed throughout the year. This was characterised by decreased activities during the start and end of year due to the resurgence of the Covid-19 pandemic. There was an increase in the number of import permits issued from 1340 in 2020 to 1465 in 2021. The number of consignments cleared increased from 2194 in 2020 to 2509 in 2021. The increase in consignments cleared can be attributed to an increase in individuals importing medicines for personal use due to reasons ranging from non-availability to high prices locally.

Enforcement

Table 13 Inspections conducted

Premises Type	**2020**	**2021**
Local Manufacturers	5	7
External Manufacturers	45	35
Cannabis Inspections	24	23
Pharmacies	109	112
Wholesalers	26	21
Industrial clinics	45	42
VMGDs	113	71
Vet surgeons	3	2
Medical Practitioners	13	4
Enforcement	86	37
Public Institutions	138	97
Supervision Checks of Licensed Premises	201	168
Closure of unsupervised Premises.	4	12

Graph 6 Inspections conducted



The number of inspections conducted throughout the year were generally low due to Covid-19 induced lockdown restrictions and staff attrition. Inspection targets for Public Institutions could not be reached. The inspections were aimed at fully supporting post marketing surveillance and sampling. The general trend for inspection of all the other premises remained similar to 2020.

Good Manufacturing Practice Inspections

The MCAZ through its various initiatives has continued to support the local industry through hosting of the quality circles in year 2021. These have continued to capacitate local industry on the compliance gaps they will be having. The facilitative roadmap pathways continued with one facility managing to attain Zazibona SADC MRH good manufacturing practices compliance. One oral solid and liquid dosage form cGMP compliant facility was licensed by the Authority through its small business support unit and one suppository manufacturing facility was given a manufacturing premises suitability licence.

The GMP inspectorate was instrumental in the Emergency Use Authorisation of vaccines where they looked at the premises and quality components of the manufacturers. The inspectorate was also part of the supply chain processes of the vaccines acquisition as they accompanied the MOHCC officials and the consignments from the sending countries.

The division through the small business unit was involved in the Emergency Use Authorisation of Oxygen manufacturing plants in Zimbabwe. This was very key as oxygen was in dire need during the pandemic. Three plants were inspected and two were authorised.

Good Supply and Distribution practice inspections

The division adopted the Good Supply and Distribution guidelines. These guidelines ensure that there is better handling and controlled storage of medical products in the supply chain. The inspectorate arm has been on an ongoing initiative to ensure that all concerned stakeholders are inspected as a baseline initiative with implementation roadmaps requested.

Small business support unit

In 2021 the Authority formed the small business support unit. This is a team of technocrats from all divisions whose role is to support local industry through the following initiatives;

i) Design of greenfield manufacturing plants guidelines.
ii) Review of proposed premises and HVAC system designs.
iii) Facilitative dossier compilation and submission
iv) Onsite quality control inspections and training of personnel.

Eight local facilities were assisted through this pathway. Two pharmaceutical manufacturers were licensed and one was upgraded through the initiative.

Compliance to ISO 17020 and WHO Global Bench Marking

- The division continued to maintain its compliance status with ISO 17020 requirements.
- The division attained the following bench marking levels;
  Licensing ML 2
  Regulatory Inspection ML 2
  Market Control ML 1

Lessons learnt and plans for the future

1. In 2020-2021 the inspectorate conducted virtual audits at facilities whose GMP status had lapsed. The following were challenges and lessons learnt;
   i. The likelihood of detecting data integrity issues and good manufacturing practices issues which are very key during routine inspections was difficult.
   ii. Time zones differences posed challenges as sometimes inspectors had to start work at 3am when inspecting companies in Malaysia amongst others.
   iii. The inclusion criteria for remote audits did not include new facilities because of the risk they posed. When the onsite inspections resumed in November 2021, these new facilities were given priority.
   iv. It was also noted that some facilities by virtue of design and classification, it was not possible to inspect their production areas and hence left the inspectors with partial impressions of the facilities.
   v. Only one facility could be conducted in a week as opposed to onsite inspections where one block is inspected in two days. Most manufacturers deemed these audits disruptive as they took longer.
2. In the period under review the inspectorate faced significant staff attrition which also affected the processes, and it became apparent that there was need for modalities to have staff retention.
3. The division hopes to have achieved WHO Global Benchmark Level 3 by end of year 2022.

Chemistry Laboratory

The Medicines Control Authority Chemistry Laboratory is a National Heath Quality Laboratory 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, World Health Organisation and African Medicines Quality Forum and development partners such as The Global Fund To Fight AIDS, Tuberculosis and Malaria, United Nations Development Programme (UNDP), United Nations Children's Fund (UNICEF). 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.

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 circulated in the medicines distribution chain down to the 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 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 Zimbabwe market.

The main objective being to protect human and animal health from consuming poor quality medicines which may introduce health challenges such as anti-microbial resistance, and resistance to lifesaving essential medicines such as ARVs, anti-TB and anti-Malarial medicines.

Laboratory Statistics

Graph 7 Samples analysed by the Chemistry Laboratory 2020 – 2021

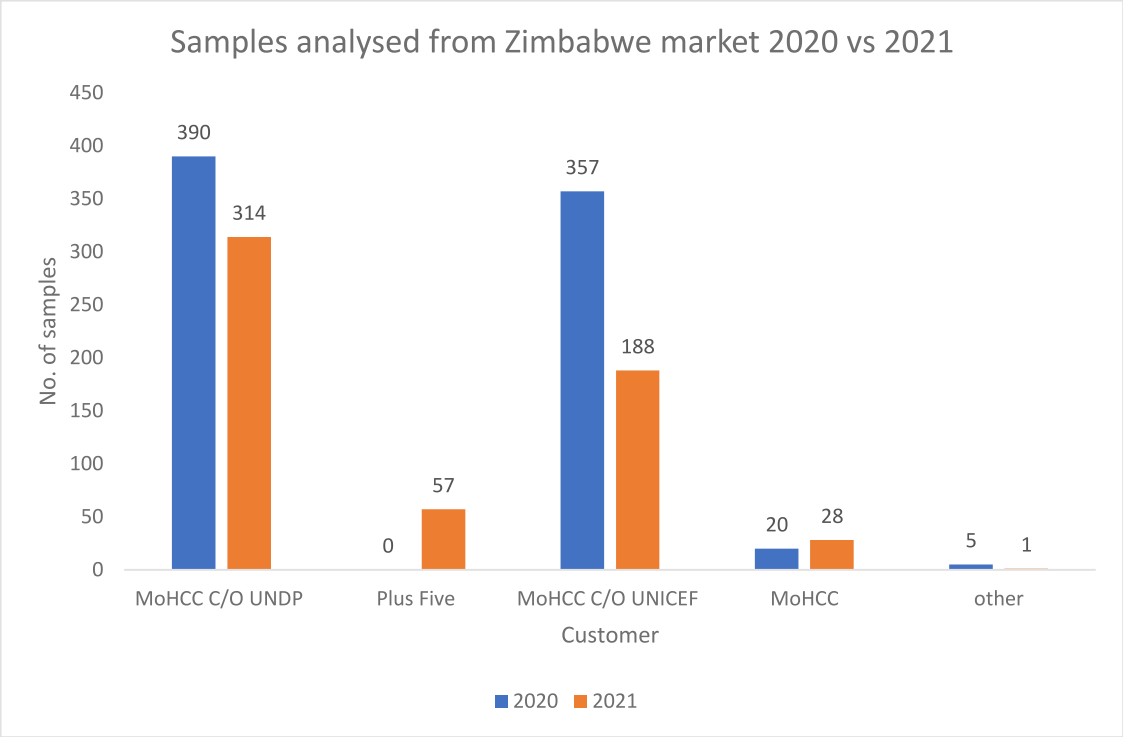


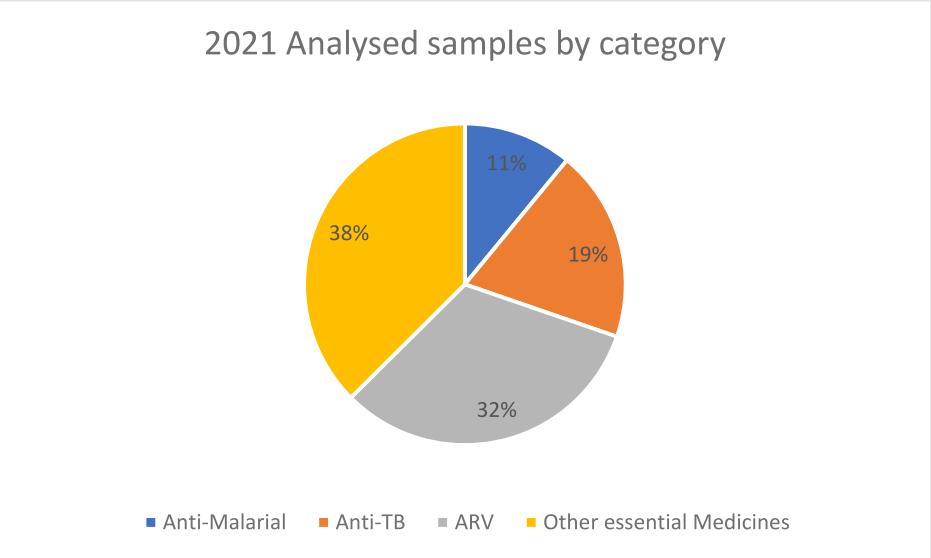
Figure 1: A comparison of samples analysed by the Chemistry Laboratory 2020 – 2021

During the year 2021, eight hundred and thirty-nine samples (839) were analyzed, (2) were cancelled. The samples analysed included medicines collected in the pharmaceutical distribution channel in Zimbabwe post market surveillance. 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.

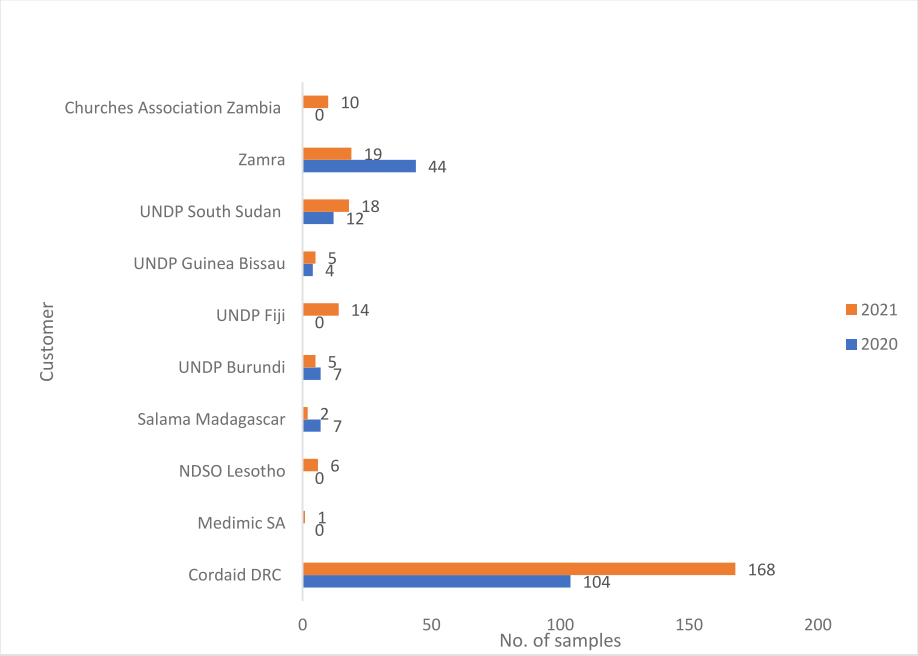
Cancellation of samples was due to unavailability of chemical reference standards and reagents due to Covid 19 induced disruptions in movement of goods.

Graph 8 Distribution of analysed samples by classification

The samples analysed included anti-malarials (11%), anti-TBs (19%), and ARVs (32%), other essential medicines (38%) as illustrated.



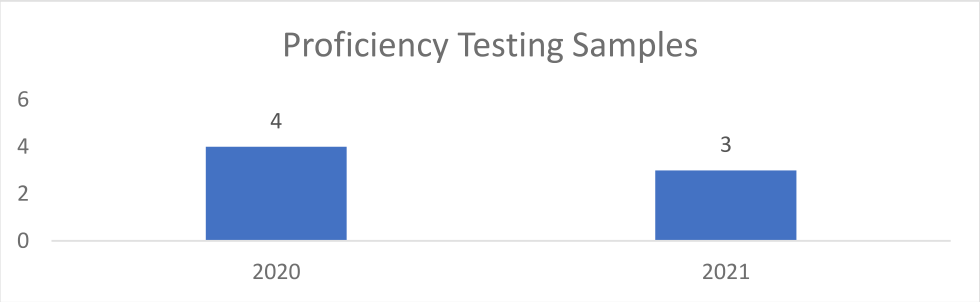
Graph 9 Samples analysed by the Chemistry Laboratory for external customers 2020 - 2021



Chemistry Laboratory

In 2021, the Chemistry Laboratory analysed samples for customers outside Zimbabwe. The samples included those brought under Global Fund/UNDP LTA from countries such as Burundi, South Sudan, and Guinea Bissau. In addition, the laboratory tested samples from Zambia, Madagascar and Cordaid, Democratic Republic of Congo (DRC).

Graph 10 Inter-laboratory proficiency testing



Samples analysed in proficiency testing schemes

The Chemistry laboratory in 2021 participated in two (2) inter-laboratory proficiency testing schemes coordinated by USP Ghana and MUHAS Pharm R&D Laboratory, Tanzania in cooperation with PTB, the German National Metrology Institute.

The techniques assessed included assay and dissolution by HPLC, Thin Layer Chromatography (TLC) and disintegration. All the Chemistry laboratory results for these techniques were considered satisfactory. In other words, all the Chemistry laboratory results were comparable to those obtained by other laboratories which participated in the proficiency testing schemes.

Achievements

The laboratory managed to continue streamlining its processes to meet its strategic plans.

i. Improved performance in terms of overall sample testing turnaround times.
ii. Retention of SADCAS accreditation for the HPLC and UV-Vis
iii. Maintenance of WHO PQ status
iv. Retaining existing external customers and partnering with new ones. Improved customer satisfaction should continue to enhance revenue streams for the organisation.

How the Unit responded to Covid-19 pandemic

As the Government of the Republic of Zimbabwe intensified the fight against Covid 19 in 2021, laboratory staff were encouraged to get vaccinated. All laboratory staff heeded the call and were vaccinated. Vaccination efforts of the government aimed at having the country to reach herd immunity and hence contain the pandemic.

As a way of decongesting the work place, arrangements were put in place for laboratory personnel to work in teams that came to work at different times. Furthermore, laboratory staff worked from home addressing non-conformities, writing standard operating procedures and other tasks that could be done offsite.

In spite of these conditions, the laboratory continued to fulfil its mandate of testing and also managed to test external samples. Safe practices like proper wearing of masking, sanitisation of hands and social distancing were enforced in the laboratory and at MCAZ in general.

Lessons learnt and plans for the future

The laboratory adapted to the new normal way of doing business through virtual meetings and trainings. The Covid-19 pandemic showed the resilience of the human spirit in conquering adversity through the adoption of information communication and technologies (ICTs).

Plans for the future

The laboratory continues to seek ways to streamline processes in order to achieve operational efficiency such as acquisition of a Laboratory Information Management System (LIMS). LIMS is a key enabler for streamlining laboratory processes including data integrity, tracking of samples and monitoring other laboratory metrics.

Microbiology Laboratory

The Microbiology laboratory is responsible for microbiological analysis of pharmaceutical preparations and allied substances. Microbiology laboratory refurbishment project, which was funded by the Global fund through United Nations Development Fund (UNDP), was successfully completed and the laboratory handed over to MCAZ in February 2021. The UNDP funding also included procurement of new equipment for the refurbished laboratory.

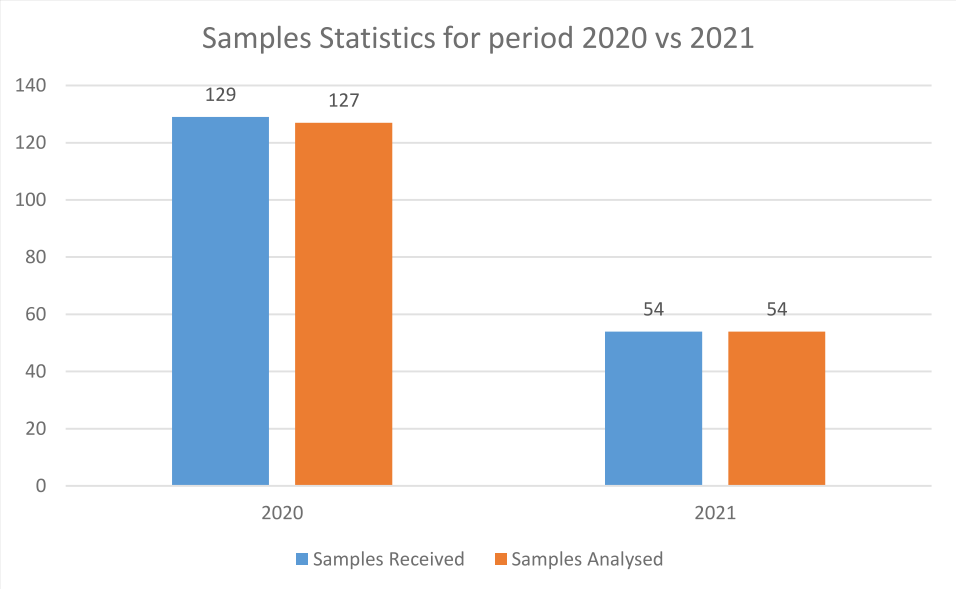
Achievements:
The refurbished laboratory now meets WHO prequalification design and layout requirements for the microbiology laboratory.

Samples Statistics Report

Table 14 Total number of samples received and tested for year 2020 and year 2021

Year	Samples Received	Samples tested
2020	129	127
2021	54	54

Graph 11 Samples statistics for period 2020 vs 2021



Comments: There was a 41.86% decrease in number of samples submitted to the laboratory for testing in year 2021 compared to 2020.

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.

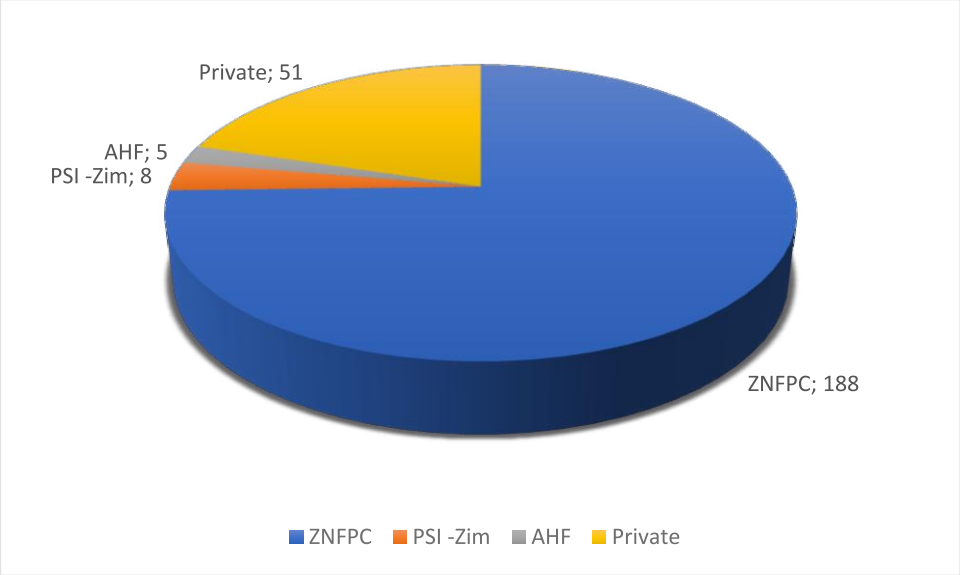
Medical Devices Unit

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

Major Highlights: 2021

Condoms

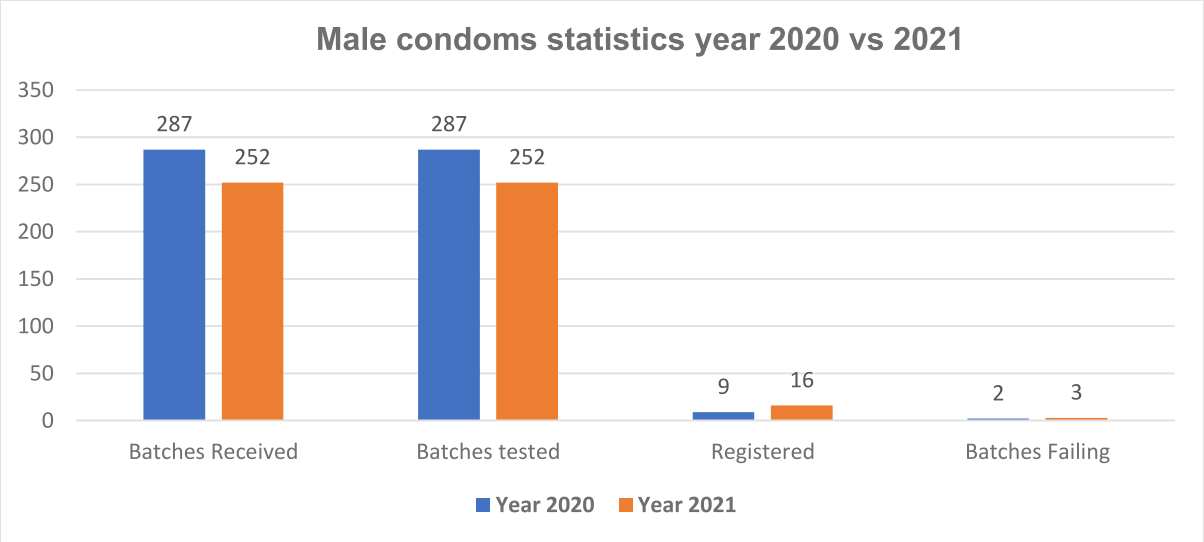
Graph 12 Condoms batches received and tested in 2021 according to source



Snapshot of batches received and tested in 2021 according to source.

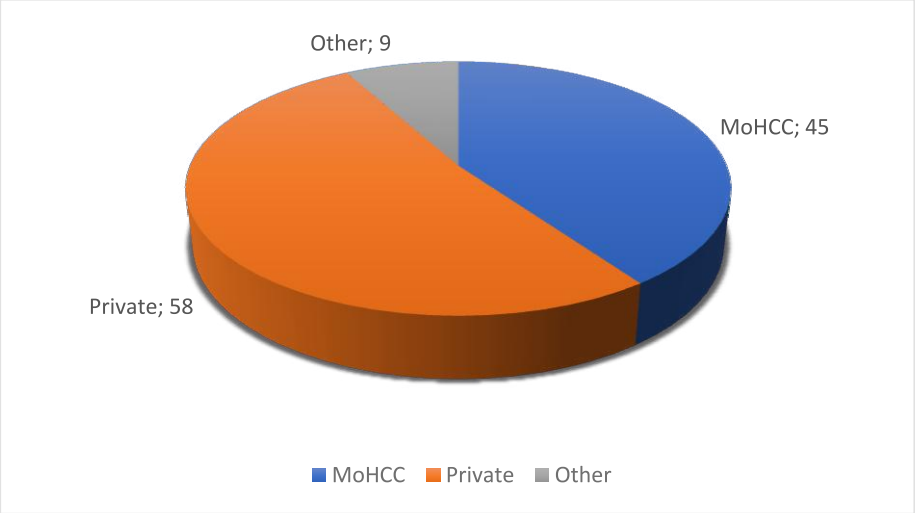
I. The laboratory received and tested two hundred and fifty-two (252) condom batches in year 2021.
ii. Three (3) batches of condoms failed quality conformity assessment tests in the year 2021. SADCAS conducted a surveillance audit in year 2021, and the laboratory maintained its ISO 17025 accreditation status.
iii. The laboratory continues to participate in annual proficiency testing schemes coordinated by the FHI360 (USA) and Enersol (Australia).
iv. There was a 12.2% decrease in the number of samples received from year 2020 to 2021.
v. There was a significant increase in new condom registered in 2020 compared to 2021
vi. The ZNFPC still provides a majority of condoms distributed in the country followed by the private sector.
vii. The three failed condom batches in year 2021 were from the private sector

Graph 13 Male condoms statistics year 2020 vs 2021



Gloves

Graph 14 Gloves received and tested 2021



Snapshot of batches received and tested in 2021 according to source.

i. The laboratory received and tested one hundred and twelve (112) batches of gloves in the year 2021.

ii. The private sector submitted approximately half of all the batches received and tested in the period with the MoHCC providing 40% of the gloves received and tested.

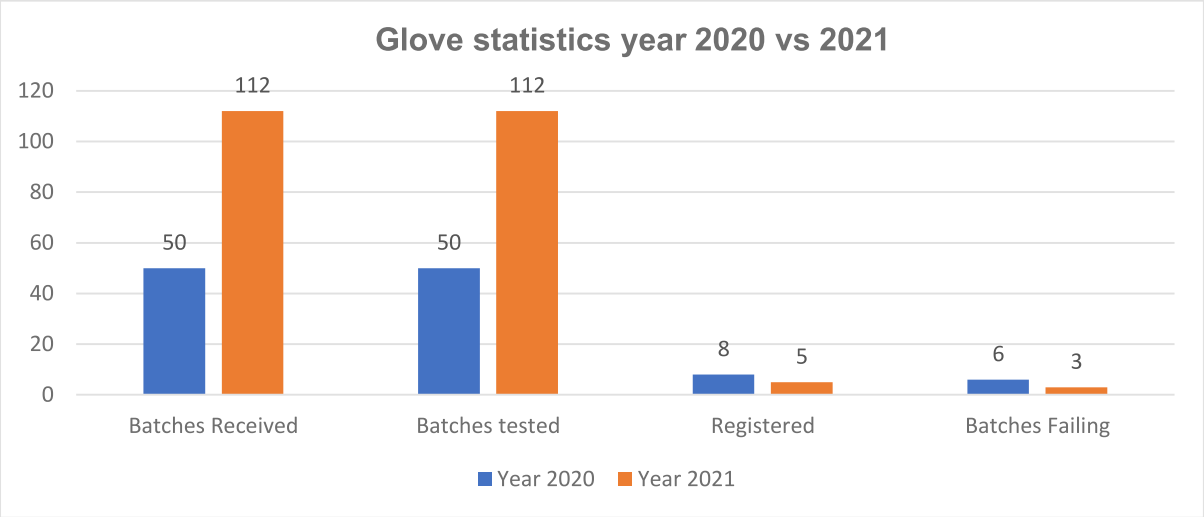
iii. The laboratory continues to participate in annual proficiency testing schemes coordinated by Enersol of Australia.

iv There was a 124% increase in the number of glove batches received from 2020 to 2021.

v. The laboratory received five (5) new glove registration applications for the period.

vi. Three (3) batches of gloves failed quality conformity assessment tests for the period.

Graph 15 Gloves statistics 2020 vs 2021



Achievements

In 2021, the laboratory managed to achieve most of its set goals. as provided in the annual work plan. More than 85% of 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 during the year. 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.

How the division responded to Covid-19

The laboratory developed an internal schedule for officers to be able to work from home. Positions in work stations/locations were also changed to ensure social distancing. Consistent use of sanitizers and mask wearing was mandatory during the period.

The laboratory had scheduled factory audits in the year 2021, which were affected by the COVID-19 pandemic. However, the laboratory resorted to virtual audits and the following challenges were encountered in the same year; communication breakdown and inadequate documentation being submitted.

Lessons learnt and plans for the future

There is a need to continuously identify processes that can be done remotely to cater for emergency situations such as pandemics or natural disasters.

Quality Unit

Provides quality oversight for the organization focusing on the following standards the organization subscribes to: ISO 9001, ISO 17025, ISO 17020, WHO GPPQCL and WHO Global Benchmarking Tool (GBT) requirements

Key/notable achievements

i. ISO 9001:2015 certification: Retained
ii. ISO 17025:2017 accreditation: The laboratories were approved for a new five-year cycle of accreditation.
iii. WHO PQ: the Chemistry Laboratory is WHO-prequalified and the Authority is working towards pre-qualification for the Microbiology Laboratory..
iv. ISO 17020:2012 accreditation: The Inspectorate Unit was approved for its first 5-year cycle.
v. WHO GBT: the Authority has been working towards attaining Maturity Level 3 for the WHO GBT. An initial assessment was conducted in August 2021 and the Authority is working on addressing the gaps identified.

Legal and Corporate Affairs Unit

In 2021, the Legal and Corporate Affairs Unit continued to execute its mandate by undertaking the following:

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

Achievements by the Legal and Corporate Affairs Unit

In 2021, the Legal and Corporate Affairs Unit made tremendous strides in fulfilling its mandate. Some of the notable achievements include the review and finalisation of the Board Charter, Legal Committee, Legal Drafting Sub-Committee and Hearing Committee Terms of Reference. The unit also facilitated the review of the Blood and Blood Components Regulations and Cosmetic Regulations by the Legal Committee and Legal Drafting Sub- Committee. We also assessed the Authority's degree of compliance to relevant legislation and compiled a compliance report. In this way we managed and mitigated the Authority's exposure to the legal risk through giving sound legal advice. The unit also participated in the WHO GBT assessment and assisted in responding to GBT requirements**.** During the course of the year we also trained employees on the Public Entities Corporate Governance Act (Chapter 10:31) through conducting corporate governance awareness sessions. We also Conducted consultative stakeholders' meetings for the draft Medicated Feed Regulations and the amendment to the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2018, Statutory Instrument 62 of 2018.

Lessons learnt and plans for the future

Valuable lessons were picked up during the course of the year. There is a 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. The Authority therefore intends to hold lobbying workshops with the parent Ministry in 2022 so as to get input on the draft legislation and ensure that it is aligned to national policies such as NDS1.The Authority will also outline the purpose of each piece of draft legislation and clarify provisions in the draft legislation at these lobbying workshops. There is also a need for the Legal Unit to actively and frequently assess the Authority's level of compliance to relevant legislation.

Information and Communication Technology (ICT)

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.

Key/notable achievements

The Unit has reached 86% on the automation of key business processes of the Authority. This is in line with our goal of reaching 100% automation. More achievements were recorded in the online services where the Unit has developed and implemented an Online portal for processing applications for authorisation of Narcotics drugs. Other online services that were developed and implemented include the Premises and Persons licence renewals, the online Helpdesk portal. The Unit developed and implemented QR Code authenticator that allows MCAZ officers to validate Licenses, Permits, Authorisation Letters and certificates. In order to protect the information and data generated by the authority, the Unit implemented a robust backup system. (VEEAM). In addition we have implemented the Network Monitoring system, intrusion detection system and a robust data protection system.

Lessons learnt

ICT needs to use benchmarking tools when giving Laptop and computer specifications to the procurement and administration unit so that when they are dispatched the Unit would check if the specifications are as required. Procurement of ICT Equipment should not solely be based on the lowest quotation available equipment as in previous years. It should be mainly based on the quality of equipment. Even though higher quality equipment cost more to purchase, they result in a much lower cost to operate, less frustrations from users and more productivity of employees.

Plans for the future

Going forward, the unit plans to close efficiency gaps identified the following systems:

i. ZIMDIS – Drug Registration and Retentions
ii. Import and Export of Registered Medicines
iii. Import and Export of Unregistered Medicines (Section 75)
iv. Online renewal of Licenses for premises and persons
v. Import and Export of Narcotics

The Unit also plans to implement the ZIMDIS Payment Portal to increase accessibility. To improve customer satisfaction, we also plan to implement the Customer Management System. We will also fully integrate Microsoft 365 into our system to improve employee productivity.

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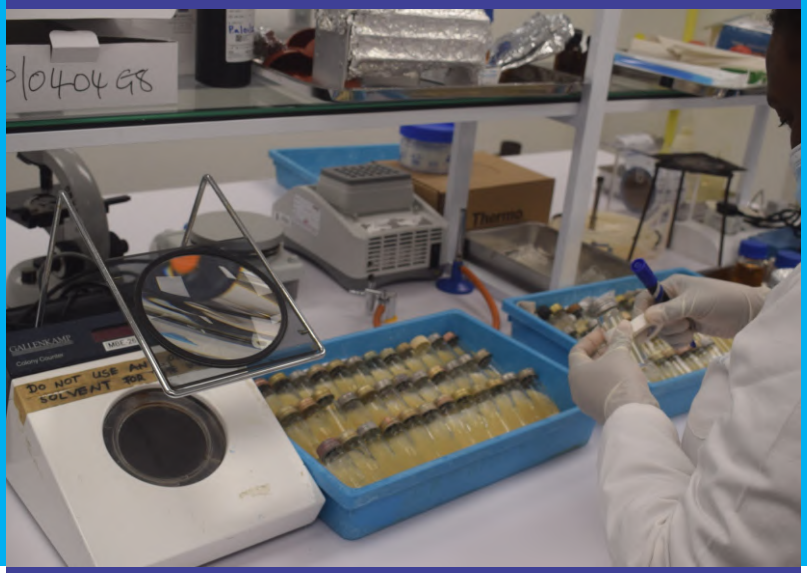

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Protecting your right to quality medicines and medical devices