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Mr Davison Kaiyo - Public Relations Officer

Editor's note

Welcome to our special 25th Anniversary magazine. This is the first time MCAZ has published a magazine to highlight and celebrate the work of the Authority. This project is mainly to mark the Authority's 25 years as an independent national medicines regulatory body.

We take this opportunity to thank all our stakeholders for their support in making this project a success.

The Medicines Control of Zimbabwe (MCAZ) was established in 1997 as a successor to the Drugs Control Council (DCC) and the Zimbabwe Regional Drug Control Laboratory. The Authority draws its mandate from the Medicines and Allied Substances Control Act (Chapter 15:03) (MASCA).

MCAZ was enacted by the Government of Zimbabwe to serve a specific purpose through the Ministry of Health and Child Care and holds the overall responsibility for ensuring good quality, safe and effective medicines and related medical products throughout the pharmaceutical value chain.

The vision of the Authority is *"to be an effective and efficient regulator for medical products and allied substances in Zimbabwe and a comparative regulator globally."* The MCAZ exists "to ensure access to safe, effective and good quality medical products and allied substances for the protection of public and animal health."

The main purpose of the MCAZ@25 is to celebrate the milestones that the Authority has achieved over the years. It is also part of the Authority's stakeholders' engagement. The pages of this magazine are packed with information from the Authority as well as congratulatory messages from various stakeholders.

This project is mainly to mark the Authority's 25 years as an independent national medicines regulatory body.

Going forward MCAZ intends to make this magazine an annual publication where the industry and the regulator will interface with each other and share information with our various stakeholders.

The purpose of this magazine is to raise awareness and inform MCAZ's stakeholders on the activities of the Authority, and the industry trends. The magazine will also seek to inform stakeholders of the latest regulatory developments. In short, the aim is to bridge the gap between the regulator and its stakeholders which include the industry players and citizens in general.

Happy Reading!

Editor

Published by: Ataraxia Communications

CELEBRATING 25 years

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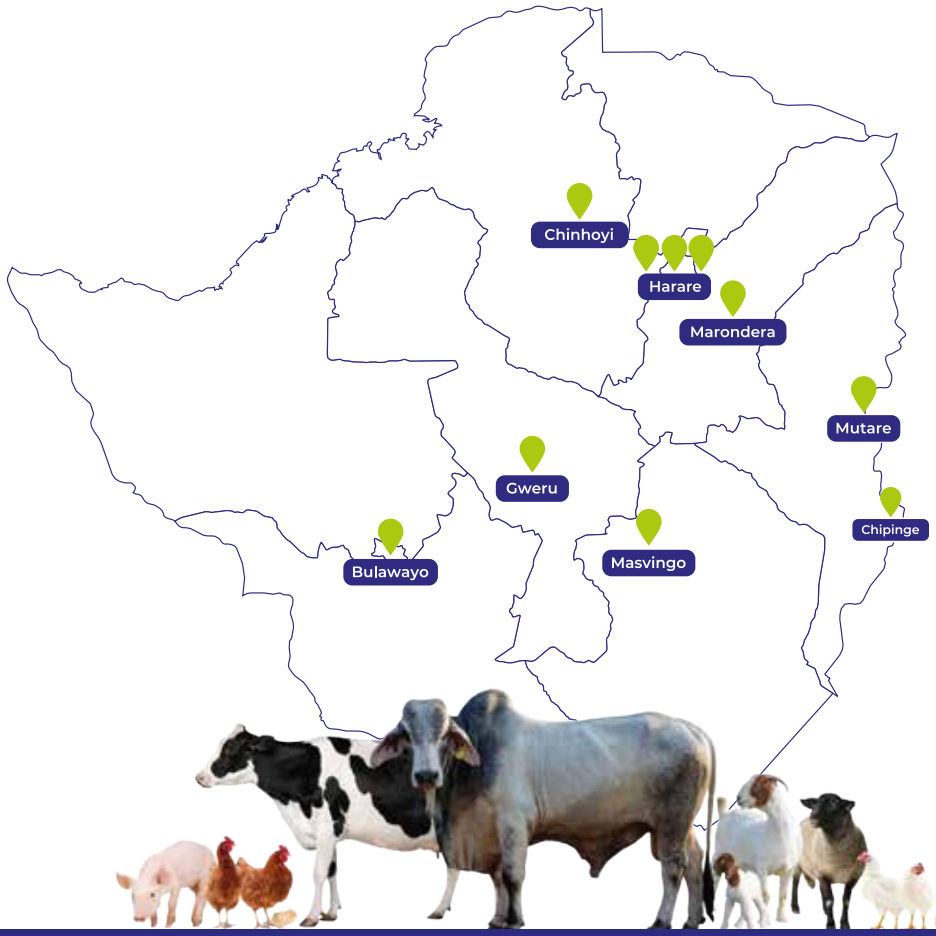

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Mr R.T Rukwata - Director-General

Foreword

The year 2022 is a special year on the calendar of the Medicines Control Authority of Zimbabwe (MCAZ). This year marks the 25th year of the existence of MCAZ as an autonomous National Medicines Regulatory Authority.

MCAZ is a statutory body established by an Act of Parliament on the 1st of August 1997. It is the successor to the Drugs Control Council and the Zimbabwe Regional Drugs Control Laboratory.

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

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

Currently, the Authority is pursuing the World Health Organization (WHO) Global Benchmarking Tool (GBT) Maturity Level 3 which means a stable and well-functioning Regulatory system. GBT represents the primary means by which the WHO objectively evaluates regulatory systems which enables WHO and regulatory authorities like MCAZ to identify strengths and areas of improvement. It also facilitates the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps, prioritize IDP interventions; and monitor progress and achievements.

Regionally the Authority has participated in the ZAZIBONA initiative as one of the founding members together with Zambia, Botswana, and Namibia. From the onset, MCAZ has been the implementing agency for this well-regarded work-sharing initiative in the Southern African Development Community (SADC). ZAZIBONA is a collaborative medicines registration initiative in the SADC Regional Economic Community focusing on joint assessments of applications for marketing authorisations and good manufacturing practices (cGMP) inspections of manufacturing facilities. ZAZIBONA was founded in October 2013 by the four countries above with the support of the WHO prequalification program and the Southern Africa Regional Program on Access to Medicines (SARPAM). The initiative has since expanded to include other SADC member states. This promotes regional integration in the area of medicine regulation.

The 25-year anniversary also came against the background of the COVID-19 pandemic. MCAZ played a critical role in the National COVID-19 response strategy. The Authority made sure that the country rolled out the national vaccination strategy successfully by issuing emergency use authorizations (EUAs) for COVID-19 vaccines and providing scientific recommendations on COVID-19 therapeutics that the country needed to protect its citizens.

The government of Zimbabwe launched the National Development Strategy 1 (NDS1) which charts policies, institutional reforms, and national priorities that the Government will be focusing on from 2021-2025.NDS1 is a key component of the Second Republic's plan and drive to achieve Vision 2030, Zimbabwe to emerge a prosperous and empowered upper-middle-income society by 2030, through a bold transformative development agenda and has succeeded the Transitional Stabilisation Programme (TSP) which ran from October 2018 to the end of 2020. This national strategy provides direction and guidance for all planning across the various sectors of the economy, and for MCAZ specifically the health sector.

The NDS 1 priorities to which MCAZ directly has a part to play are Health and Well-being, Good Governance, Moving the Economy up the Value Chain and Structural Transformation (Pharmaceutical value chain), and Human Capital Development. MCAZ plays a pivotal role in ensuring access to good quality, safe and effective medicines, and medical devices.

Since the Authority's establishment in August 1997, the environment in which MCAZ operates has undergone fundamental scientific, technological, legislative, and social changes. The scope of the Authority's work has expanded to include medicinal cannabis regulation and complementary medicines.

This magazine shares the Authority's history and development over the preceding 25 years, and we hope it will provide meaningful insights to all our stakeholders into the workings of MCAZ, past, present, and future.

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Management team

Standing left to right: *DR Z.A. Makoni, Mr T. Mukanga, Mr L. Chirinda, Mr K. Dzawo, Mr T.A. Gonho, Mrs A. Chokowore, Mrs P. Nyambayo, Mr C. Shamhuyarira, Ms C. Mvurume, Mrs R. Gwata, Mr T. Vambe*
Seated from left to right: *Dr T. Munhenga, Mr R.T. Rukwata (Director General), Dr M. Chiware (Authority Chairperson) Mrs C Samatanga-Dandira, Mrs R. Chimhenga,* ***Missing:*** *Ms T Muvirimi, Mr F Masekela and Ms R.Tugwete*

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Happy anniversary.

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University of Zimbabwe-Clinical Trials Research Centre (UZ-CTRC)

UZ-CTRC is a center of research excellence within the University of Zimbabwe that has operated continuously for the past 28 years to conduct clinical trials in the prevention and control of HIV, TB and other co-morbidities. With support from the community, health research regulators, international collaborating universities and local health authorities, research findings have contributed to the understanding of HIV epidemiology and pathogenesis, informing global and Zimbabwean health policy and enhancing clinical practice. Over 80 research studies relating to HIV and TB prevention and treatment, and recently COVID-19 have been successfully completed. Studies include Phase I-IV clinical trials to support licensure of novel bio pharmaceutical products and for new indications of registered products. Research activities are implemented by 7 clinical research sites in Harare and Chitungwiza. These are supported by onsite pharmacies and laboratories equipped with modern equipment such as ISO 7 clean rooms with certified Biosafety Cabinets. UZ-CTRC operates highly equipped, ISO 15189 accredited diagnostic Laboratory situated within Parirenyatwa Group of Hospitals. The laboratory provides real-time safety assessments for study participants enrolled in pharmacokinetic and safety clinical trials. The biorepository with –20C°, -80°C and vapour phase liquid nitrogen storage capacity currently holds over 800 000 specimens. UZ-CTRC remains committed to mentor and train the next generation of biomedical research leaders in sub-Saharan Africa. We have persisted with the mission to conduct and implement our research in a manner that drives public policy.

We congratulate the Medicines Control Authority of Zimbabwe for reaching 25 years of regulating and supporting the conduct of clinical trials in Zimbabwe. We acknowledge the excellent relationship and support we have received from the Pharmacovigilance and Clinical Trials Division, and we look forward to your constant growth and achieving the WHO Maturity Level 3 in the near future!

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Over the times you have well carried out your mandate to protect the entire country's right to quality medicines and medical devices. We cherish your consistency in improving our alignment to this goal. To many more years of coexistence, **Happy Silver Jubilee!**

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Sky Pharmaceuticals, a distributor of quality pharmaceutical products in Zimbabwe, congratulate you on this key milestone and we look forward to continuing to work together with MCAZ.
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Wishing you more success and all the best for your organization in the coming years.

HISTORY OF MCAZ

Regulation of medicines in Zimbabwe began in 1969 through an Act of Parliament, the Drugs and Allied Substances Control Act of 1969 (Chapter 15.03) . Globally, medicines regulation is constantly evolving and Zimbabwe attempts to stay abreast of current trends. This resulted in the promulgation of the Medicines and Allied Substances Control Act in 1997. The Act created an autonomous agency independent of the fiscus, the Medicines Control Authority of Zimbabwe (MCAZ).

The Medicines Control Authority of Zimbabwe (MCAZ) therefore, is a state-owned enterprise established by an Act of Parliament. MCAZ was enacted by the Government of Zimbabwe to serve a specific purpose through the Ministry of Health and Child Care and holds the overall responsibility for ensuring good quality and safe medicines and related products throughout the pharmaceutical value chain.

The Authority commenced operations on the 1st of August 1997 as a successor of the Drugs Control Council (DCC) and the Zimbabwe Regional Drug Control Laboratory (ZRDCL). The Commemorations will allow us to reflect on past successes attained and the challenges the Authority has overcome over the 25-year journey. The jubilee celebrations will help the Authority to plan for future improvements as it strives "To be an effective and efficient regulator for medical products and allied substances in Zimbabwe, and a comparative regulator globally."

The Authority's 25th Anniversary represents an opportunity to communicate with a wide cross-section of our stakeholders. It is a perfect opportunity to articulate our mandate. And it is also an opportunity to thank employees, suppliers and clients who have helped the Authority reach these milestones. The Anniversary is also significant because it reminds all stakeholders of the critical role the authority plays in public health and how over the years it has strived to fulfil its mandate.

The country through the Ministry of Health and Child Care (MoHCC) in its Strategic Plan (2021 -2023), emphasizes the need for improved access to essential medicines and commodities, the harmonization of quantification, procurement, warehousing, distribution and the promotion of local manufacturing of medicines and medical products for import substitution. The government of Zimbabwe also launched the National Pharmaceutical Strategy (2021-2025). The strategy aims to improve the local production of drugs, thereby increasing the availability of the country's essential medicines and exporting excess drugs. The objectives of the Strategy include the following the need to increase the market share of local pharmaceutical products from the current 12% to 35% by 2025; to increase local production of essential medicines from US$31.5 million to US$150 million by 2025; to increase local production of essential medicines from 30% to 60% by 2025; and to improve exports of pharmaceutical products from 10% to 25% by 2025. This strategy is the first one in the history of Zimbabwe, to improve the local production of drugs thereby increasing the availability of the country's essential medicines and exporting excess drugs so that

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

Zimbabwe becomes a net exporter of medical consumables.

MCAZ has paid particular attention to its responsibility in the strategy, with the establishment of a Small Business Support (SBS) Unit in 2021, to provide local manufacturing support and facilitative assistance, under the Key Programme of Bio-Medical Engineering, Bio-Medical Science, Pharmaceutical and Bio-Pharmaceutical Production. The Ministry's thrust is to increase local medicines manufacturing to imported medicines ratio from 20:80 to 80:20. In line with the various issues highlighted at a national and sector level, MCAZ has developed a five-year strategic spanning (2022-2026) which takes cognisant of, and supports the national agenda as set in National Development Strategy 1 (NDS1) and in line with 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 maximizing the use of locally available resources in line with the Primary Health Care approach.''

The National Pharmaceutical Strategy also seeks to promote Good Manufacturing Practices (GMPs). GMP is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. The MCAZ through the GMP inspectors supports local manufacturers so that they comply with GMP making sure that the products are manufactured under internationally recognized standards.

This Results-Based Strategic Plan seeks to communicate the MCAZ vision, mission, key result areas, impacts, outcomes, strategies, major programmes, outputs, and direction to its employees, clients, stakeholders, and partners. It also establishes a road map of the strategic results, programmes, projects, and activities that the MCAZ will focus on in the short to medium term. The initiatives from this strategic plan will be evaluated on the achievement of the anticipated results in terms of the MCAZ budgets, performance contracts, annual work, and performance monitoring plans in the planning period.

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25th Anniversary

1997 - 2022

Bestzone Pharmacies would like to extend heartfelt congratulations to the Director General and the entire staff of MCAZ on the organisation's 25th anniversary.

We acknowledge MCAZ's dedication and commitment towards fulfilling their duty to safeguard human and animal health in Zimbabwe by effectively regulating medications, allied substances and medical devices. Bestzone is happy to be associated with MCAZ and excited about their continued path in their striving to be a competent and efficient regulator.

Congratulations, makorokoto, amhlope!

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- Regulation of Veterinary Medicines in Zimbabwe

Over the past 25 years, the scope of activities carried out by Medicines Control Authority of Zimbabwe (MCAZ), has been refined in response to demands for services that MCAZ is in a strategic position to give.

Legislation

The enactment of Medicines and Allied Substances Control (Complementary Medicines) Regulations of 2015, paved way for the evaluation of nutraceutical and herbal based medicines meant for humans. The Veterinary Committee in later in years used the same Regulations to approve nutraceutical and herbal medicines meant for animal use.

Following the adoption of a proposal to develop fit-for-purpose veterinary legislation, MCAZ has been working at separation of the Medicines and Allied Substances Control (General) Regulations SI 150 of 1991 to come up with standalone veterinary medicines regulations. The drafted Medicines and Allied Substances Control (Veterinary Medicines) Regulations cater for issues such as withdrawal periods when used in food producing animals and inclusion of the target species in which veterinary medicines would be use, to name but a few.

Antimicrobial Resistance (AMR) is currently one of the greatest threats to global and national health systems. A situational analysis of AMR in Zimbabwe in the human health, animal health and environmental sectors was conducted in 2016 were the Veterinary Unit of MCAZ played a key

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role in gathering information with other stakeholders. One of the major drivers of AMR in the country was identified as the widespread use of antimicrobials in animals in the absence of a prescription or the oversight of veterinarians. The global quadripartite, WHO, FAO, WOAH and UNEP, recommended its member states to develop legislation to control the use of antimicrobials. The MCAZ, in consultation with different stakeholders, has drafted the Medicated Feed Regulations which will serve to control the use, overuse and misuse of antimicrobials in medicating feed for food producing animals. These regulations will strengthen the country's response in fighting AMR.

Guidelines

Zimbabwe has a regulatory approval process that entails subjecting all veterinary medicines to premarketing evaluation, to ensure compliance to national laws and adherence to international best practices. MCAZ assesses applications for registration of veterinary medicinal products, conducts good manufacturing practices inspections of facilities that manufacture medicines as well as performance of quality control tests of these medicines there by ensuring that all animal medicines are safe, efficacious and of good quality. A list of registered veterinary medicines is gazetted annually, and these medicines can be used as standard interventions in the treatment of animals.

In the last decade there has been development of veterinary specific common technical document guidelines for registration of veterinary medicines as well as specific guidelines for registration of veterinary vaccines in Zimbabwe.

The MCAZ in conjunction with the Department of Veterinary Services Dipping Committee, have developed a joint guidance document for the conducting of dipping trials on cattle acaricides in Zimbabwe. These guidelines are used to evaluate applications for dipping trial protocols used to conduct dipping trials to determine safety and efficacy of new acaricide or dip chemicals developed by industry.

International and regional cooperation

The MCAZ was appointed by World Organization for Animal Health (WOAH) formerly OIE to be the focal point for veterinary medicinal products. Each year, the Veterinary Unit submits Zimbabwe's antimicrobial consumption (AMC) import/export data of veterinary medicines to WOAH. This practice has helped the Authority monitor antimicrobial consumption data over the years.

The Veterinary Unit participates at the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Outreach forum. Through this forum MCAZ contributes to developing harmonized guidelines for authorization of veterinary medicines as well as post authorization requirements. Joining VICH paved way for adoption and development of the MCAZ guidelines for registration of VMPs and veterinary vaccines.

The Medicines Control Authority of Zimbabwe is a coordinator and active member of a regional veterinary medicinal product harmonisation initiative for SADC which allows for joint assessment of dossiers, joint Good Manufacturing Practices inspection and joint pharmacovigilance activities, under the Veterinary Medicines ZaZiBoNa Collaborative procedure. Also, party to this initiative are Botswana, South Africa, Tanzania, Zambia, Namibia and Malawi. Such initiatives enhance the rigors which veterinary medicines are subjected to. Only the most efficacious, safe and of good quality, should find its way to the public. This harmonization platform follows on the successes of the ZAZIBONA collaborative procedure for human medicines, the EAC and WAEMU/UEMOA initiatives. These were efforts directed at improving collaboration, reducing duplication of work and standardizing approaches to assessment of medicines in the region.

Tackling Antimicrobial Resistance

Veterinary Unit has been very much involved in authoring One Health AMR National Action Plan in 2017 with other multisectoral stakeholders drawn from the ministries of health, agriculture, environment, pharmaceutical industry, private laboratories, private sector as well as civil society organisations. The Veterinary Unit co-chairs the Rational Medicines Use technical working group (TWG) of the AMR Core Group together with the Directorate of Pharmacy Services of Ministry of Health and Child Care. This technical working group is responsible for ensuring that there is rational medicines use in human and animal health. The Rational Medicines Use TWG has received a Grant from the Multipartiner Trust (MPTF comprised of development partners WHO/FAO/WOAH), covering 2022 and 2023, aimed at fighting against illegal products, substandard and falsified medicinal products within Zimbabwe. The TWG future plans are to enhance antimicrobial stewardship in both human and animal health.

Current efforts

Challenges in the veterinary medicines value chain, has led to perennial shortages and emergence of unorthodox supply routes. The proliferation of illegal, substandard and falsified veterinary medicines has grown exponentially. In response to this challenge the Licensing and Enforcement Division (LED), is now engaged in mapping the distribution of unregistered, substandard, falsified (SF) products as well as implementing other interventions to curb marketing of such products, with the help of other stakeholders. The Veterinary Unit is assisting LED to implement the MPTF Grant in this SF detection exercise.

Coordination with other national institutions

The MCAZ co-regulates the dipping chemicals for cattle acaricides with the Department of Veterinary Services Dipping Committee. Currently there is a proposal to co-opt the MCAZ into the DVS Dipping Committee to improve decision making and reduce duplication of work by the two institutions.

The MCAZ is a member of Standards Association of Zimbabwe (SAZ) Feedstuff TWG, which is responsible for the development and update of companion and food producing animal feed standards. The Authority ensures that antimicrobials that may be incorporated in feed are entirely for prophylaxis, metaphylaxis and treatment only. The use of antimicrobials for growth promotion is discouraged in these feed standards.

The MCAZ provides a course in forensic pharmacy to the University of Zimbabwe Bachelor of Veterinary Science students. Forensic pharmacy ensure that veterinarians are conversant with laws governing the use of veterinary medicines within Zimbabwe.

Future plans

Though still rudimentary, MCAZ is developing veterinary medicines pharmacovigilance guidelines and is putting in place a reporting system on identification of possible adverse events following the use of marketed VMPs in animals.

Conclusion

In conclusion, dialectics is to social scientists what symbiosis is to natural scientists. The MCAZ is there to serve society and to fulfill its mandate, the community it serves should complement its efforts. As we celebrate our silver jubilee together, let us take the necessary steps to guaranteeing public and animal health. Practice good hygiene, ensure biosecurity standards are observed, administer medication to animals especially antibiotics with the supervision of a veterinarian. Do not use antibiotics for growth promotion or disease prevention in animals, carefully dispose of leftover medicines and avoid sharing prescriptions.

CELEBRATING MCAZ 25TH Anniversary

Wishing you many more years of unparalleled success and unrivaled corporate services. Congratulations on this special year. Happy Anniversary!

Congratulations, Makorokooto, Amlophe on thier Jubilee!!!

Celebrating 25 years of protecting public and animal health

On behalf of the Board, Management and Staff of Trinity Pharmacy, we would like to extend our heartfelt congratulations to MCAZ on attaining 25 years of protecting public and animal health by ensuring that accessible medicines and allied substances and medical services are safe, effective and of good quality through enforcement of adherence standards by manufacturers and distributers.

We wish you all the success for many more years to come.

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MCAZ IN COMMUNITY

As part of its corporate social responsibility (CSR), the MCAZ gives back to the community through the provision of scholarships to deserving students. There are two scholarships on offer- the MCAZ Scholarship and the Dr Emilio Mazhindu Scholarship. The Dr Emilio Mazhindu is named after the late former chairperson of the Authority. Below are some of the beneficiaries of the two scholarships.

FULL NAME OF BENEFICIARY	SPONSORSHIP PERIOD	DEGREE PROGRAMME	COMMENTS
Donovan Dube	2007 Part 4	Bachelor of Pharmacy UZ	Worked for MCAZ in EVR as Regulatory Officer from 1st March 2008 to 31st August 2012.
Rutendo Deve	2007 to 2008 Part 3 and Part 4	Bachelor of Pharmacy UZ	Worked for MCAZ in LED as Regulatory Officer from 1st June 2009 to December 2011.
Tariro Sithole	2007 to 2008 Part 3 and Part 4	Bachelor of Pharmacy UZ	Chief Regulatory Officer – Human Medicines D1, in EVR Division, MCAZ
Caroline G. Samatanga	2007 to 2008 Part 3 and Part 4	Bachelor of Pharmacy UZ	Chief Regulatory Officer – Licensing D1, in LED, MCAZ
Brighton Chateya	2009 to 2010 Part 3 and Part 4	Bachelor of Pharmacy UZ	Worked for MCAZ in PVCTas Regulatory Officer, from August 2011 to September 2013. Working in retail pharmacy in Chiredzi
Portia Kampota	2009 to 2010 Part 3 and Part 4	Bachelor of Pharmacy UZ	Worked for MCAZ as Regulatory Officer in LED from 1st November 2011 to 31st October 2014
Linda Mudyiwenyama	2009 to 2010 Part 3 and Part 4	Bachelor of Pharmacy UZ	Regulatory Officer, C5, EVR Division, MCAZ. Resigned 31st August 2022
Charlton Tsopotsa	2009 to 2010 Part 3 and Part 4	Bachelor of Pharmacy UZ	Regulatory Officer, C4, EVR Division, MCAZ.
Tatenda Nyamandi	2012 to 2013 Part 4	Bachelor of Pharmacy UZ	Regulatory Officer, C3, PVCT Division, MCAZ
Nigel Akim Muzangaza	2012 to 2014 Part 3 and Part 4	Bachelor of Pharmacy UZ	Regulatory Officer, C3, PVCT Division, MCAZ
Yvonne Tafadzwa Mberi	2013 to 2014 Part 3 and Part 4 (Dr Emilio Mazhindu)	Bachelor of Pharmacy UZ	Pre-Registration Pharmacist, C2, EVR Division, MCAZ
Brilliant Samunda	2014 to 2015 Part 3 and Part 4	Bachelor of Pharmacy UZ	Regulatory Officer, C4, EVR
Kevin Tamirepi	2015 to 2016 Part IV (Dr Emilio Mazhindu)	Bachelor of Pharmacy UZ	Regulatory Officer, C3, PVCT
Martha Mwatseteza	2014 to 2017 Part II to Part 4	Bachelor of Pharmacy UZ	Regulatory Officer, C4, LED
Mercy Magava	2015 to date Part III	Bachelor of Pharmacy, UZ	Regulatory Officer, C3, PVCT
Success Munyengwa	July 2016 to July 2018	Bachelor of Pharmacy	Regulatory Officer, C3, PVCT
Clive Kamhoti	2016 to 2018 Part 3 to Part 4 (Dr Emilio Mazhindu)	Bachelor of Pharmacy	Regulatory Officer, C4, LED
Hardlife Dera	2018 to 2019 Part III to Part IV	Bachelor of Pharmacy HIT	Regulatory Officer, C2, LED
Rhoda Mudare	2017 to 2019 Part 3 to Part 4	Bachelor of Pharmacy, UZ	Regulatory Officer, C3, LED
Rufaro Mbanje	2017 to 2019 Part 3 to Part 4	Bachelor of Pharmacy, UZ	Regulatory Officer, C3, EVR
Kudzai L. Mkhau	2018 to 2019 Part 4	Bachelor of Pharmacy, UZ	Regulatory Officer, C3, LED
Arnold Kunaka	(Dr Emilio Mazhindu) 2019 to 2020 Part 4	Bachelor of Pharmacy, UZ	Regulatory Officer, C2, LED
Raymond Manjengwa	2019 to 2020 Part 4	Bachelor of Pharmacy HIT	Regulatory Officer, C2, LED
Onias Hove	Part III and Part IV 2020 to 2021	Bachelor of Pharmacy, UZ	Pre-Registration Pharmacist, C1, PVCT
Evylyne Tapudzai	Part III and Part IV 2020 to 2021	Bachelor of Pharmacy, UZ	Pre-Reg Pharmacist, C1, PVCT
Tavonga S. Chanyuka	Part III in Aug 2022	Bachelor of Pharmacy, HIT	Part III Student at HIT
Trishie Chikerema	Part IV in Aug 2022 (Dr Emilio Mazhindu)	Bachelor of Pharmacy, HIT	Part IV Student at HIT
Tadiwa Tapfumaneyi	Part IV in Aug 2022	Bachelor of Pharmacy, UZ	Part IV Student at UZ

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Quality Unit & Laboratory Services

1.0 Preamble

As a National Medicines Regulatory Authority, the MCAZ`s regulatory systems play a key role in assuring the quality, safety, and efficacy of medical products. Effective, efficient and transparent regulatory systems are consequently an essential component of overall health systems and contribute to desired public health outcomes. The Authority subscribes to the following international standards and guidelines to ensure compliance and maintenance of a solid regulatory system.

1. ISO/IEC 17025:2005 standard for General Requirements for the Competence of Testing and Calibration laboratories.
2. ISO/IEC 17020:2012 standard for Conformity Assessment-Requirements for the Operation of Various Types of Bodies Performing Inspections.
3. ISO 9001:2015 standard for Quality Management System requirements.
4. Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) for WHO Pre-Qualification.

The Authority has a Quality Unit that ensures implementation and maintenance of its Quality Management System (QMS) through the various standards and guidelines.

2.0 The journey to accreditation and certification

The journey began with the laboratories which were accredited to ISO 17025:2005 in 2010 by the South African National Accreditation System (SANAS).

The Chemistry laboratory was accredited for the following tests and techniques:

HPLC technique on
(i) Identification
(ii) Dissolution
(iii) Uniformity of content
(iv) Assay

UV-Vis Spectrophotometry technique on
(i) Identification
(ii) Dissolution
(iii) Assay

The Medical Devices laboratory was accredited for the following tests/methods:
(i) Air Inflation
(ii) Water-Leak test
(iii) Package Seal Integrity
(iv) Dimensions test

The Chemistry laboratory was WHO-Prequalified in 2014**.** This was an assessment by WHO to confirm that the laboratory meets the recommended international norms and standards for the analysis of products.

After the first cycle of accreditation by SANAS, the Authority migrated to the Southern African Development Community Accreditation Services (SADCAS). The laboratories were accredited to ISO 17025:2005 in 2015 by SADCAS receiving a new 5-year cycle.

Plans were in place to ensure the whole organisation was accredited. Preparations for the certification began and in 2016, the Authority was certified to ISO 9001:2015 in 2018 by the Standards Association of Zimbabwe (SAZ).

To ensure adherence to standards in the Inspectorate Unit, the Authority pursued accreditation to ISO 17020:2012 and in 2020, the Inspectorate Unit was accredited to ISO 17020 by SADCAS.

The Authority has been subscribing to these standards and has had 5-year renewals for accreditation and 3year renewals extended for certification after the end of each cycle.

3.0 Current projects:

1. **WHO Prequalification for the Microbiology laboratory**
   The Microbiology laboratory was refurbished, and the Authority is now working towards prequalification of the laboratory.

2. **WHO Global Benchmarking Tool (GBT).**
   This is a tool used for benchmarking regulatory systems. The GBT is designed to evaluate the overarching regulatory framework and the component regulatory functions. It also incorporates the concept of Maturity Level or ML (adapted from ISO 9004), allowing WHO and regulatory authorities to assess the overall maturity of the regulatory system on a scale of 1 (existence of some elements of regulatory system) to 4 (operating at advanced level of performance and continuous improvement).
   The Authority was assessed in August 2021 and is aiming to achieve ML 3 after addressing the identified the gaps, formulating and implementing its Institutional Development Plan (IDP).
   The Authority also looks to adopt more standards as it expands its operations to include more medical devices and other products.

4.0 The Authority Quality Unit

The Authority has a Quality Unit that ensures implementation and maintenance of its Quality Management System (QMS) for the whole organisation through the various standards and guidelines.

Happy

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25 Years E

Eunice Muzhanye

I joined the then Zimbabwe Regional Drugs Control Laboratory (ZRDCL) on the 26th of May 1996 as a Copy Typist for the Medical Devices laboratory which was stationed at Queensdale site.

In 1997 I then transferred to the Head Office at 106 Baines Avenue to work as a Typist in the Typing Pool. In August 1997, ZRDCL and Drugs Control Council (DCC) being government entities merged to become a Parastatal: [Medicines Control Authority of Zimbabwe (MCAZ)]. I joined the newly formed MCAZ as a Typist commencing 1998.

I was promoted to a Unit Secretary for the Chemistry, Microbiology and Medical Devices laboratories in the year 2005 to date. This responsibility included taking minutes for the Laboratory Committee Meetings, among other meetings.

Over the years, I have gained valuable experience as I contributed towards the attainment of the IS0/IEC 17025 accreditation status of the Medical Devices and Chemistry Laboratories, certification of MCAZ to ISO/IEC 9001 and the attainment of the WHO Pre-Qualification status for the Chemistry Laboratory.

Tinashe Gonho

My motto for the 25 years has always been:
Working hard for something we don't care about is called STRESS
Working hard for something we love is called PASSION
Always give the world the best you have

- Pursuing is not a one time job
- It is a way of life
- Hidden o the prudent of this world and ONLY revealed to babies

Bertha T Chingwe

I have been the face of MCAZ for the past 25 years. Many of our customers have heard my voice a number of times. I have seen many come and go and the experience has been rewarding. I have been part of MCAZ as a receptionist, having joined the then Drugs Control Council and Zimbabwe Regional Drug Control Laboratory. I have experienced the transformation and gained a lot of experience interacting with customers from different organisations both on the phone and while they wait in the reception area.

Ruka Maningi

I have seen a lot in the 25 years that I've been part of this organization uh which traces its root from the Ministry of Health as the then Drugs Control Council. It then we moved to this current premises. I've seen the organization grow to where it is today. All these buildings that we see today were not there and for me that's growth. Over the years I've also seen the mandate of the MCAZ expand and I'm glad to have been part of this growth and expansion. I really appreciate the Authority and different management who came through over the years for all that they have done in my life and that of my colleagues. I am proud of my contributions to this organization as I look forward to my retirement.

xperiences

Francisca Chimbidze

When I joined the organization, I was responsible for making tea for management and glassware in the Microbiology laboratory. This was way back whilst it was still the Drugs Control Council. During those days we were using the Msasa and Queensdale offices. With time and growth, other employees joined in and roles were split I was now responsible for glassware in the Microbiology lab only. I've worked with a number of Director-Generals from the days of Dauramanzi to the current Director-General and I'm very grateful for the opportunity to be part of this critical organization in the health delivery system of Zimbabwe. I am still attached to the microbiology laboratory, and it is a wonderful experience working there.

Phillah Dziva

The working conditions at MCAZ are very good as evidenced by my long stay here. We work as a family, and they've seen the family grow over the years. I've learnt a lot over the years even my children at home know a lot about MCAZ and like me, they are also appreciative of the role that the MCAZ has played in our lives. I've managed to send my children to school and build a house for them. The togetherness and the family spirit that has prevailed over the years I hope it continues.

Munakandafa Mutasa

It's been years since I set foot at MCAZ, it was 25 October 1994, and that's when I started my journey and it was the Drugs Control Council and Zimbabwe Regional Drugs Control Laboratory then. I was appointed as an assistant laboratory technician in a newly created unit under chemistry (as a contract worker) – the Chemical Reference Standards unit. It was headed by Mrs C Kanjere, and we were responsible for the generation of Secondary chemical reference standards. By then I was a National certificate candidate with the Harare Polytechnic. In the year 1998, MCAZ was formed, and I was appointed as a Junior Analyst in the Laboratory Services unit (Chemistry). By then I was a National Diploma holder in Applied Chemical Technology. The project for the production of secondary standards was stopped. This is the time when the issue of the Quality Management system started. In 2004 I completed my Higher National Diploma and was promoted to the position of Analyst from 2005 -2009. In 2007 I completed my B-Tech in Chemical Technology with NUST and in 2009 was promoted to a Senior Analyst position till today. We were the pioneers of SANAS accreditation in 2010. In 2014 we attained WHO PQ Status. In 2015 we migrated from SANAS accreditation and in came SADCAS. We have managed to maintain our accreditation status and WHO PQ since then. Currently, we are working on WHO GBT. I grew up with the organization from my boyhood till I became a man. I have seen people go and new ones join, and others re-join. In short, MCAZ has been my life and I believe will retire at MCAZ. During my prime-time opportunities came but decided to remain with this organization and would wish it grows bigger and decentralize some of its Units.

MCAZ

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The Cospharm Investments (Zimbabwe) Chief Executive Officer, Management and entire staff compliment would like to congratulate the MCAZ on its 25th anniversary of regulatory excellence. We continue to applaud all efforts by the Authority to ensure that all regulations regarding medicine manufacture, distribution and retailing are adhered to by all industry players. We value the continued support offered by the Authority to enable the pharmaceutical industry to thrive and compete with worldwide standards.

Congratulations, Makorokoto, Amhlope!

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A quarter century of medicine-safety monitoring:

The Zimbabwe National Pharmacovigilance Centre

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. In simple terms, pharmacovigilance is monitoring the safety of medicines, and taking appropriate action.

The Medicines Control Authority of Zimbabwe (MCAZ) is the National Pharmacovigilance Centre and has been a member of the World Health Organisation (WHO) Programme for International Drug Monitoring since 1998. As part of this programme, the MCAZ works together with the other member states to monitor medicines safety and take appropriate action to protect the public. The operations of the centre are based on the WHO guidelines for setting up and running a National Pharmacovigilance Centre.

As the national pharmacovigilance centre, the MCAZ identifies signals of drug safety such as unknown or poorly characterized adverse events in relation to a drug and communicate the information in a way that improves therapeutics and promotes patient safety. Through the National Pharmacovigilance Centre, which is housed in the Pharmacovigilance and Clinical Trials (PVCT) division the MCAZ also undertakes assessment of risks and options for risk management. Furthermore, PVCT 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

To page 34

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From page 32

When medicines are approved for use, it is because they present a clear benefit to society. Unfortunately, no medicine is completely risk-free, therefore medicines are approved when the benefits clearly outweigh the risks. The specific aims of pharmacovigilance are to:

- improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions,
- improve public health and safety in relation to the use of medicines,
- contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use, and
- promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

How pharmacovigilance works

Reporting of adverse events (side effects) is a key component of pharmacovigilance, and it is important for patients and healthcare professionals to report any suspected adverse events to the MCAZ. There are various methods available for reporting adverse events, including electronic reporting from the MCAZ website, https://www.mcaz.co.zw, under online services, mobile app reporting, and paper reporting forms available from healthcare institutions and the MCAZ offices.

Different types of individual case safety reports are processed, including the following:

- Adverse Drug Reaction (ADR) reports
- Adverse Event (AE) and Serious Adverse Event (SAE) Reports
- Adverse Events Following Immunisation (AEFI) Reports

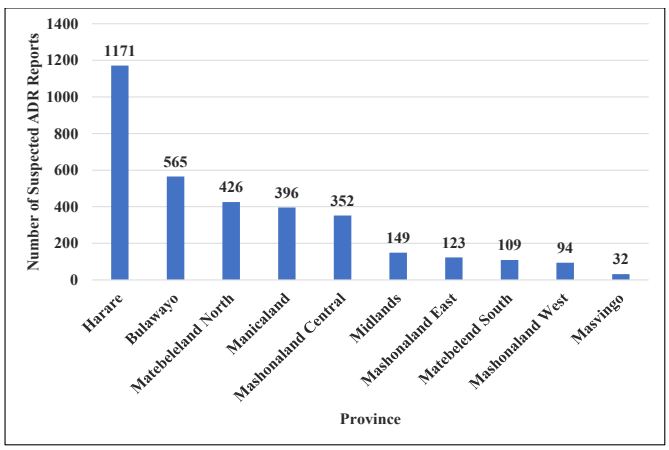
These reports can all be accessed from several available platforms listed below:

- Paper forms available and healthcare institutions and the MCAZ offices
- Electronic reporting via the MCAZ website
- Electronic reporting through the use of mobile applications (Android and IOS)
- Electronic reporting through the use of VigiMobile
- In-person at the MCAZ offices
- Via email, mcaz@mcaz.co.zw
- Via telephone: +263-4-736981/5; 708255; 792165; 0772 145 191/2/3

Evolution of PV

The pharmacovigilance programme in Zimbabwe has matured over the course of the past 25 years, from1 adverse drug reaction (ADR) report in 1998, to over 6000 reports to date having been processed.

ADR reports received in the last 10 years (2012 to 2022) by province



Some key pharmacovigilance activities over the past quarter century involve the following:

1. Spontaneous Reporting Programme (1997 to date)
2. Targeted Spontaneous Reporting of ARVs and anti-TB medicines (2012 to date)
3. Cohort Event Monitoring of Artemisinin Combination Therapies (Malaria medicines) 2008 to 2012
4. Cohort Event Monitoring of the H1N1 vaccine
5. Adverse Event Following Immunisation (AEFI) monitoring of routine child immunisation
6. AEFI monitoring of COVID-19 vaccines (2021 to date)
7. Stimulated Telephone-Assisted Rapid Safety Surveillance (STARSS II) project (2020 to date)
8. Publication of relevant safety-related circulars and alerts
9. Publications in reputable peer-reviewed journals
10. Publication of regular Medicines Information Bulletins
11. Enhanced AEFI surveillance of Typhoid Conjugate Vaccines (TCV) HPV & Cholera 2019 to 2022
12. Establishment of Good Vigilance Practices (GVP) requirements for manufacturers/Applicants of registered medicines
13. Regional collaborations, e.g. the SPaRCS project (Strengthening Pharmacovigilance and Regulatory Capacities in 4 countries, namely South Africa, Namibia, Eswatini and Zimbabwe)

Challenges

The main challenge facing the pharmacovigilance system in Zimbabwe is under-reporting. The MCAZ, together with the Ministry of Health and Child Care (MoHCC) as well as donor partners regularly conduct awareness trainings to promote reporting of adverse events.

Submission of incomplete reports, or reports with insufficient data is another challenge, and this is mitigated through regular trainings and stakeholder engagements.

Positives

- There has been a positive response from many stakeholders, including MoHCC public health programmes over the years, resulting in an increase in the reporting of adverse events. This has resulted in an improvement in patient reporting and consequently in patient safety.
- The electronic reporting system launched in 2019 enables faster and more efficient evaluation of submitted reports

Way forward

Continued monitoring of medicines is essential for the MCAZ to fulfil its mandate of protecting public and animal health, and this can only be achieved if all the stakeholders work together, including the patients and healthcare professionals, to report all suspected adverse events

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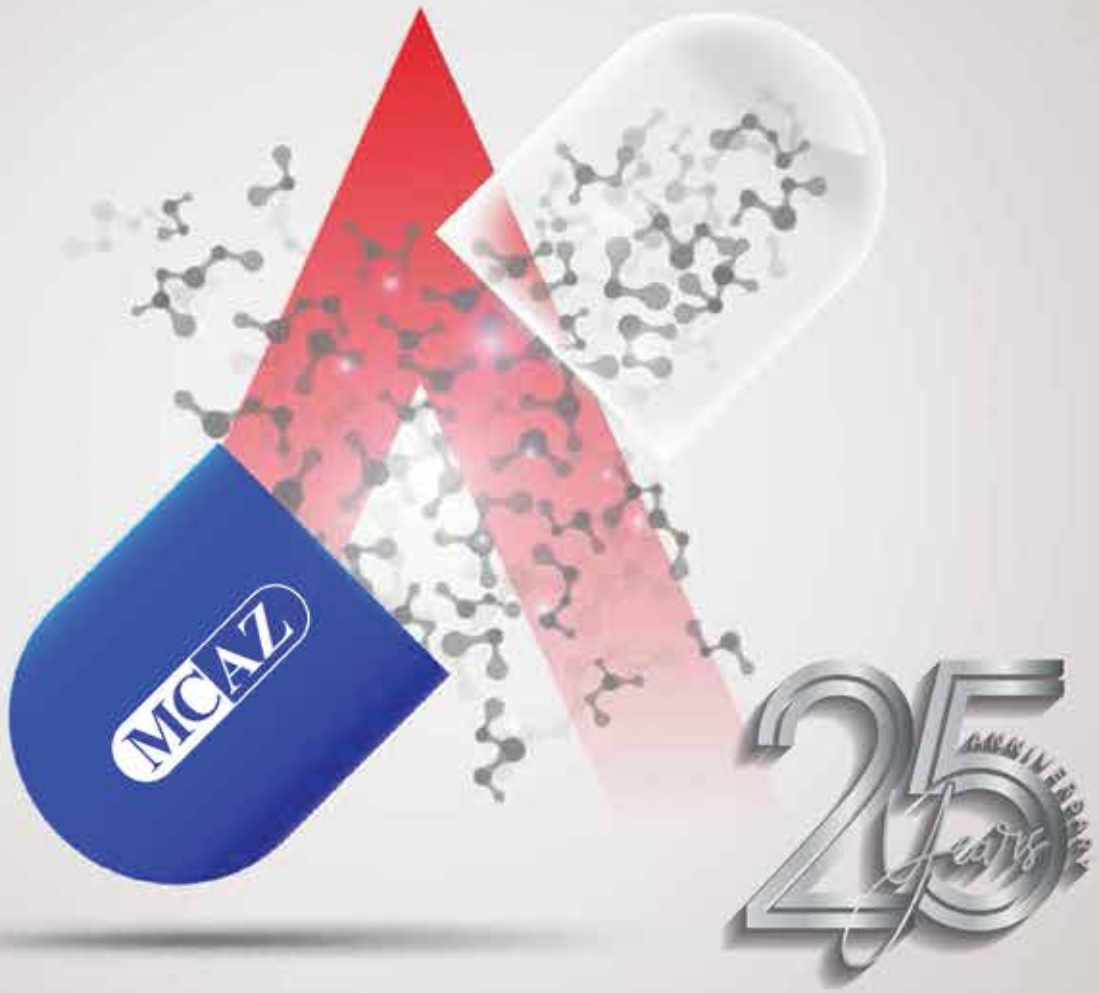

Congratulations to the MCAZ for your Silver Jubilee, celebrating 25 years.

With you, for you

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The Licensing and Enforcement Division

Introduction

The Licensing and Enforcement Division (LED) is the inspectorate arm of the MCAZ. The inspectors are mandated by section 66 of the Medicines and Allied Substances Act (Chapter 15:03) to inspect all premises handling medicines in Zimbabwe. The Unit also work in conjunction with port health and custom officials at the ports of entries, as well as work with the police on enforcement of all medicines legislation in Zimbabwe. There are three units in the Licensing and Enforcement division, namely the Enforcement Unit, the Licensing Unit and the Import and Export

Control Unit.

The role of the Enforcement unit is to inspect all the approved and licensing facilities in the country.

Inspectors checks public clinics and hospital and in the process also conduct post marketing surveillance of all medicines in the public sector. This ensure that medicines that are distributed in the public sector are safe, efficacious and of good conditions. During the inspection of the public sector premises, inspectors verify that medicines are being stored according to the approved storage conditions and they are dispensed according to the approved regulations.

The inspectorate division also ensures that all licenced private premises i.e pharmacies, dispensing medical practitioners premises, wholesale dealers, veterinary medicines general dealers, manufacturers, industrial clinics and veterinary institutions meet the minimum requirements as provided by the third schedule of the Medicines and Allied Substances Control Act. During inspection of these premises, the Authority also ensures that the public is protected by ensuring that the personnel who supervise these premises are qualified and are licensed, the medicines are properly stored, there is no sell of unapproved unregistered medicines and there is no sale of expired medicines.

The enforcement division works hand in hand with the police in the enforcement of MASCA and related legislation. The MCAZ inspectors conduct combined blitz and enforcement inspections with the police. The Authority's inspectors act as expert state witnesses and draft affidavit statements for crimes related to medicines. The inspectors are involved in the training of the police on the legislation that governs pharmaceuticals in Zimbabwe. Every year trainings are conducted in all the 10 provinces of the country, and they include participants from the Judiciary Services Commission, the National Prosecuting Authority, the Police, Customs, and the Port Health. These trainings have been done over the years so that these stakeholders are well equipped when handling matters referred to them that are related to pharmaceuticals.

The inspectorate conducts current Good Manufacturing Practices Inspections throughout the World to support product registrations. During these inspections, MCAZ's competent inspectors inspect general oral dosage manufacturing facilities, sterile manufacturing facilities, vaccine manufacturing facilities, and veterinary manufacturing facilities among others. These inspections are done to ensure there is the ultimate protection of the general public on the medicines that are found throughout the Zimbabwean supply chain. During these inspections, the inspectors verify the manufacturing procedures, the materials used, the personnel, and adherence to set World Health Organisation standards and other guidelines. A total of close to 100 facilities are inspected every year.

The Licensing Unit issues licenses to pharmacists, doctors, pharmacy technicians, and nurses and also licenses the premises from which these personnel work. The licensing unit ensures that all applications for licensing of new premises are compliant, and it conducts inspections of new premises before issuance of licenses. The Unit works in collaboration with other stakeholders such as UZ, HIT, and ICHE in offering continuing health education and forensics lectures.

The licensing unit enforces the Dangerous Drugs Act and its regulations on behalf of the Ministry of Health and Child Welfare. In this role, the Authority maintains the national narcotics allocation quota and monitors its use. MCAZ also inspects all premises that handle dangerous drugs for compliance.

The Unit issue narcotic licenses to all importers and manufacturers and participate in the International Narcotics Control Bureau activities on behalf of the government of Zimbabwe.

The import and export unit is involved in the execution of the statutory instrument for import and export control of medicines S.1 57 of 2008. They ensure that all medicines to be imported into the country and to be exported out of the country are of good quality and have all the necessary quality requirements. The inspectors from this unit are stationed at some of the ports of entry where they do physical verification of consignments coming into the country.

Milestone Achievements of the Past 25 years

i. The inspectorate over the past 25 years has managed to set up a well-trained and coordinated enforcement arm.
ii. The Unit has managed to ensure that all licensed and approved facilities are inspected at least once in 2 years.
iii. LED has managed to set current Good Manufacturing Practices Road maps with the local manufacturing industry. These resulted in capacity building and increased compliance by

the local manufacturing industry.

iv. We have managed to set good liaison relations with other enforcement agencies such as Police, ZIMRA, NPA, and Port Health amongst others and we train more than 100 officers from these agencies yearly.

v. LED also managed to ensure that all facilities with medicines submitted for registration are inspected and that there is compliance verification from all of them routinely.

vi. The LED has developed user requirement specifications for most of our manual systems into electronic systems. This has resulted in the complete online application of premises and person licenses, import and export permits, narcotic licenses applications, and section 75 medicines applications amongst others. This has shortened the processing timelines and contributed to the ease of doing business.

vii. The MCAZ's inspectorate has been the implementing agency for the ZaZiBoNa medicines harmonization fora. As the brainchild idea of the former MCAZ's director general and other director generals in the SADC region, this harmonization program has seen milestone achievements being done. These include quarterly harmonized inspections and desk reviews and assessments which have resulted in ease of doing business in SADC.

viii. The inspectorate has been very influential in the training and setting up of other regional agencies. This has seen inspectors from countries like Tanzania, Botswana, Uganda, and Malawi coming to be trained in-house and onsite for different inspectorate activities.

ix. The inspectorate has reduced malpractice amongst licensed professionals through a number of initiatives such as the point system which have resulted in the methodical handling of offenders and passing of penalties that are deterrent.

x. The LED has also put in place guidelines for setting up greenfield manufacturing facilities and we have also been very pivotal in the small business support unit which is involved in facilitative regulatory initiatives. This has resulted in many new pharmaceutical manufacturers for conventional medicines and those for complementary medicines setting shop in the country in line with the National Development Strategy 1 (NDS1).

xi. The Unit was very pivotal during the Covid pandemic by being the first National Medicines Regulatory Agency that conducted virtual audits. A total of almost 150 facilities were remotely audited during the pandemic.

xii. The officers from the inspectorate were very influential in ensuring the availability of good and efficacious Covid Vaccines. This involved evaluation of the dossiers submitted for emergency use authorization, evaluation of the consignments in the sending units, and also at the ports of entry.

xiii. MCAZ officers were involved in the setting up of the country's local medical gas manufacturing facilities which were very beneficial during the Covid pandemic.

Plans for the next 5 years.

1. The inspectorate is envisaged as the leading inspectorate in SADC that can be relied upon by other national medicines regulatory agencies.
2. The unit also envisages increased current good manufacturing practices compliance by our local pharmaceutical industry and increased space uptake by new players.
3. The LED envisages more regional participation and also MCAZ inspectorate being designated a centre of inspections and regional centre of excellence.
4. The reduction in drug peddling and increased surveillance capacity in the country through collaborative efforts by different agencies.

The MCAZ 's inspectorate would like to commend the continued relationship that has been developed with the Ministry of Health and Child Care in ensuring increased compliance in the public sector. The Inspectorate also would like to thank the various professional fraternities under its mandate on increased self-regulation. The inspectorate would like to thank its stakeholders such as the ZRP, ZIMRA, NPA, Port Health, and JSC for all the various collaborations that have improved medicines regulations in the country. The inspectorate further thanks the local pharmaceutical manufacturing industry for all their efforts to ensure they meet the minimum cGMP requirements.

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Cozycare pharmacies would like to congratulate the Medicines Control Authority of Zimbabwe (MCAZ) on their 25th anniversary. We are proud to be associated with such a milestone and wish the Authority all the best in it's pursuit of protecting Zimbabwe from harmful medicines.

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Pharmacovigilance in Zimbabwe – The Journey and updates

Introduction:

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicines/vaccines-related problem. The Medicines Control Authority of Zimbabwe (MCAZ) is the National Centre for Pharmacovigilance (PV) implemented by the Pharmacovigilance and Clinical Trials (PVCT) Division and national PVCT Committee that is also the national AEFI Committee. The Zimbabwe National Pharmacovigilance Policy Handbook 2016 and Guidelines for COVID-19 AEFI surveillance guidelines 2021 provides a framework for the pharmacovigilance system in Zimbabwe in line with the Medicines and Allied Substances Control Act Chapter 15:03 and Circulars 3 /2022 and 13/2022. Zimbabwe is a participating member of the World Health Organisation Programme for International Drug Monitoring (WHO PIDM) since 1998 to date, through the MCAZ national PV centre.

Progress highlights:

Since 2012 to date, the MCAZ in collaboration with the Ministry of Health and Child Care PHPs embarked on a strategy of strengthening pharmacovigilance of through integration of PV into public and private health programs using Smart Safety Surveillance (3S) concept initiatives. The MCAZ receives and monitors adverse reaction reports from approved clinical trials conducted in Zimbabwe, pharmaceutical industry, Adverse Events Following Immunization (AEFIs) from both public and private health clinics and hospitals. This included HCWs trainings in all provinces, districts including consumer engagement through radio shows, advertisements, Med Safety promotions and online mobile safety reporting tools and PV projects. Over two thousand HCWs were trained and issued certificates of attendance for train the trainer model resulting in promotion of patient safety and increased reporting rates. The 3S projects included active cohort event monitoring (CEM) of antimalarials, Targeted Spontaneous Reporting (TSR) of Antiretrovirals, Antituberculosis medicines and other essential medicines, enhanced AEFI surveillance of all vaccines during vaccines launches and campaigns including mHealth participant centred active surveillance of all vaccines and COVID-19 vaccines. As a result, a total of 6 077 reports were received at by MCAZ from 1998 to 2022 of which 3595 (59.2%) were ADRs mostly related to antiretrovirals, 1033 (17.0%) were SAEs from clinical trials and pharmaceutical industry, 1110 (18.3%) from vaccines and 339 (5.5%) from COVID-19 vaccines. The PVCT Committee conducted causality assessment conducted for all these safety reports and most of these safety reports were known non-serious reactions that resolved without sequel. The national AEFI Committee consist of 11 specialist members who conducts monthly causality assessment of each safety report (ADRs/AEFIs/SAEs) to determine if the adverse reaction(s) were due to the medicine or vaccine. Feedback and PVCT Committee decisions for all the submitted safety reports was sent to all reporters, provinces, districts sites , reporters, and healthcare workers (HCWs) through emails, signed letters, medicines information bulletin , manuscript publications, PV training sessions in all provinces and Zimbabwe Expanded Program on Immunization(ZEPI), Ministry of Health and Child Care (MoHCC) review meetings. The information gathered from pharmacovigilance activities is used to identify medicines and safety related problems to communicate the information to HCWs and consumers/patients in way that minimize further occurrences of ADRs/ SAEs/AEFIs and continuously promote patient and consumer safety. Where the occurrence of such safety concerns known as signals are medicines and vaccines related such as interactions or allergic reactions this will also be documented in the products safety information leaflets guiding prescribers and consumers accordingly in benefits and risk minimisation measures.

Roll out of electronic medicine and vaccine safety reporting tools:

- The MCAZ launched the Consumer web-based reporting form available on the MCAZ website, hyperlink: https://primaryreporting.who-umc.org/ZW in 2016 for reporting of adverse events and adverse reactions after vaccination or medicine intake.
- In 2019, MCAZ launched the electronic – Pharmacovigilance (e-PV system) available on the MCAZ website, hyperlink: https://e-pv.mcaz.co.zw. The e-PV system is a custom-built software which allows users to submit adverse events/ reaction reports directly to MCAZ.
  The e-PV system is also available via desktop applications on Windows, Linux and Mac operating systems and via mobile applications (titled "MCAZ Pharmacovigilance" on Google Play Store and "MCAZ PV" on the Apple App Store).
- The MCAZ in collaboration with the MoHCC-ZEPI and the WHO rolled out the VigiFlow and VigiMobile electronic tools for Adverse Events Following Immunisation (AEFI) reporting. All 11 provinces were trained in a national training held on the 27th of February 2023 to the 1st of March 2023. Subsequent provincial and district VigiFlow/VigiMobile trainings to are scheduled for March 2023 to train all 63 districts and 1741 health facilities in Zimbabwe.
- For anyone concerned that they might be experiencing a suspected side effect after vaccination or taking any medicine, it is important that they immediately contact or visit their health care provider to get immediate medical assistance if required. The healthcare providers are encouraged to report the adverse event/ reaction reports to the MCAZ.

mHealth Participant Active Centered (MPAC) Adverse Event Following Immunization (AEFI) surveillance known as Stimulated Telephone Assisted Rapid Safety Surveillance (STARSS II) project was conducted by MCAZ from 2020 to 2022 at Chitungwiza Central hospital and Citimed Private hospital. The goal of STARSS (II) project was to investigate the feasibility of utilizing mobile-Health (mHealth) for active AEFI surveillance in Zimbabwe including COVID -19 vaccines safety monitoring and to strengthen pharmacovigilance in Zimbabwe. The project explored the use of SMS and cellphone calls to communicate with the participants' guardians and/or adult vaccine recipients after vaccination. The study sites were Chitungwiza Central Hospital and Citimed Private Hospital. Data analysis indicated that the mHealth tool was more effective in detecting AEFIs and acceptable by consumers and healthcare professionals. As part of strengthening AEFI surveillance, the MCAZ and MoHCC signed an agreement with WHO Uppsala Monitoring Center in quarter 3, 2022 to launch a new mobile AEFI surveillance system known as VigiMobile that will be deployed in 2023.

Good Vigilance Practice (GVP) by Pharmaceutical Industry

In 2000, MCAZ made a mandatory policy communicated in circular 4/2000, requiring all Marketing Authorization Holders (MAHs) to report

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suspected ADRs, SAEs and/or AEFIs that occur in Zimbabwe. The scope of vigilance has been further expanded and clarified through the Pharmacovigilance Policy Handbook and publication of the Pharmacovigilance Guidelines for Pharmaceutical Industry, and MCAZ circulars 3/2022 and 13 /2022. Manufacturers and MAHs are required to set up a vigilance system of their medicinal products and designate a responsible person for Pharmacovigilance (PV) or a Qualified Person for Pharmacovigilance (QPPV) to oversee the pharmacovigilance system. MCAZ Regional collaboration and Regulatory Centers of Excellence (RCORE) Initiatives in pharmacovigilance and clinical trials regulation. The MCAZ PVCT Divisions has conducted several regional vigilance and clinical trials regulation courses for other national regulatory agencies over the years and in collaboration with Medical Research Council of Zimbabwe (MRCZ), European Development Clinical Trials Partnership (EDCTP) related projects such as - SPaRCS (Strengthening Pharmacovigilance and Regulatory Capacities in four Southern African countries) project, SEARCH project, and Paul Enrlich Institute Global Health Vacci train and Blood Train (haemovigilance) project.

Acknowledgements:

The MCAZ and National Pharmacovigilance Center takes this opportunity to sincerely thank the public, consumers, patients, health care providers and all pharmacovigilance stakeholders MoHCC public and private sector. Thanks to the MCAZ and partners for funding medicines and vaccines safety monitoring activities including technical support/funding from intergovernmental partners such as CHAI, GAVI, Global Fund/ UNDP UNICEF, STARSS Project University of Adelaide, Australia, World Health Organization (WHO), as part of health systems strengthening and quality assurance initiatives.

MCAZ offers RCore trainings

The Medicines Control Authority of Zimbabwe (MCAZ) was designated a Regional Centre of Regulatory Harmonisation under the African Medicines Regulatory Harmonisation (AMRH) initiative of the African Union and the Nepad agency in 2014, offering training and services for new and seasoned regulators from national medicines regulatory authorities, regulatory affairs personnel from the pharmaceutical industry and people from academia.

The areas of RCORE designation included:

- Medicines registration
- Pharmacovigilance and clinical trials
- Laboratory testing of medicines

The MCAZ RCORE mission

To provide world class medicines regulatory training expertise so as to ensure affordable, quality, safe and efficacious medicines for the African continent.

The MCAZ RCORE vision

To have an adequate pool of knowledgeable well trained medicines regulators for Africa and to grow the MCAZ brand through the RCore activities.

Goals/ objectives of the MCAZ RCore

- To ensure that Africa has access to safe, quality, efficacious and affordable medicines through regulatory excellence (overarching goal)
- To nurture and develop technical and managerial competencies to ensure effective medicines regulation in Africa.
- To build and develop the same competencies as stipulated in the Nepad RCore Framework at MCAZ as a pilot and use the pilot as a solid example

- Provision of academic, technical and managerial training to regulators and analysts on this regulatory function;
- Skills enhancement through hands-on training, twinning and exchange programmes among national medicines regulatory agencies
- Implementation of national or regional programmes in support of coordinations of activities between official medicines control laboratories
- Exchange information on work programmes to optimise the use of expertise, laboratory resources and analytical data available

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The National Pharmaceutical Company (NatPharm) Board, Management and St
like to congratulate the Medicines Control Authority of Zimbabwe (MCAZ) on t
Anniversary. NatPharm, which is the nation's sole procurer of medicines for pub
facilities enjoys cordial relations with MCAZ and the two organisations are
dependent. We would like to commend MCAZ for remaining committed to providi
quality, accurate and timeous service to all its stakeholders. More so the org
constantly seeks ways to meet and improve the requirements of all its customers

NatPharm is also mandated to store and distribute medicines and medical su
public health facilities and shares the same objective with MCAZ which is respo
protecting public and animal health by ensuring that accessible medicines a
substances and medical devices are safe, effective and of good quality through
ment of adherence to standards by manufacturers and distributors.

MCAZ has for years diligently executed its mandate to protect public health ensu

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medicines and medical devices on the market are safe, effective and of good quality.

NatPharm pledges complement MCAZ's efforts in ensuring access to affordable, safe and quality medical products for the citizenry.

MCAZ's vision to be an effective and efficient regulator for medical products and allied substances in Zimbabwe, and a comparative regulator globally is certainly within reach.

Makorokoto, Amhlope, Congratulations!!!

Zazibona Collaborative Initiative

The MCAZ has been the implementing agency for the ZAZIBONA which is the collaborative medicines registration initiative in Southern Africa focusing on dossier assessments and good manufacturing practice (cGMP) inspections. It was founded in October 2013 by four countries Zambia, Zimbabwe, Botswana and Namibia with the support of WHO prequalification and the Southern Africa Regional Program on Access to Medicines (SARPAM). The name ZAZIBONA is a combination of the first two letters of the name of the founding countries and coincidentally means 'to look to the future' in a local Zambian language, nyanja. The name ZAZIBONA has been retained even though the membership has grown from the four founding countries to all 16 SADC countries. The initiative was formally endorsed by the SADC Ministers of Health in 2014 and became part of the SADC medicines registration harmonisation (MRH) project in 2015.

Objectives

ZAZIBONA is a collaboration in assessments and GMP inspections for medicines registrations with objectives to:

1. Reduce workload
2. Reduce timelines to registrations
3. Develop mutual trust and confidence in regulatory collaboration
4. Establish a platform for training and collaboration in other regulatory fields

Participating Counties

Active Member Countries

Non-Active Member Countries

Work done to date

A total of 384 products have been submitted at country level to be considered through the Zazibona harmonisation. A total of 41 joint assessors meetings have been conducted to date. A total of 60 inspections have been jointly conducted and a total of 32 desk reviews have been jointly assessed.

How to get hold of us

Email: gmp@mcaz.co.zw or www.zazibona.com for more information.

MedOrange Pharmacies

Medorange Pharmacies is honored to join MCAZ in celebrating it's 25th anniversary. Since 1997, you have been an invariable force in improving and standardising health care bodies in Zimbabwe, inspiring us to raise the bar when complying with public health policies. Thank you for consistently excellent service, and here's to many more years of distinction to come. #stronger together.

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Medicines Control Authority of Zimbabwe

25th Anniversary

1997 - 2022

Aravas would like to extend heartfelt congratulations to the Director General and the whole staff of the Medicines Control Authority of Zimbabwe (MCAZ) on the organisation's 25th anniversary.

We recognize the MCAZ's devotion and commitment as they fulfill their duty to safeguard human and animal health in Zimbabwe by effectively regulating medications, related substances, and medical devices. Avaras is glad to be associated with MCAZ and thrilled about their path as they continue to strive to be a competent and efficient regulator. Congratulations

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MCAZ staff in pictures











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6. Blessing Bondamakara
7. Shamar Juru

TEN (10) YEARS
1. Charity Mutsata
2. Tendayi Munhenga

FIFTEEN (15) YEARS
1. Albert Maqolo

TWENTY (20) YEARS
1. Edith Jiri

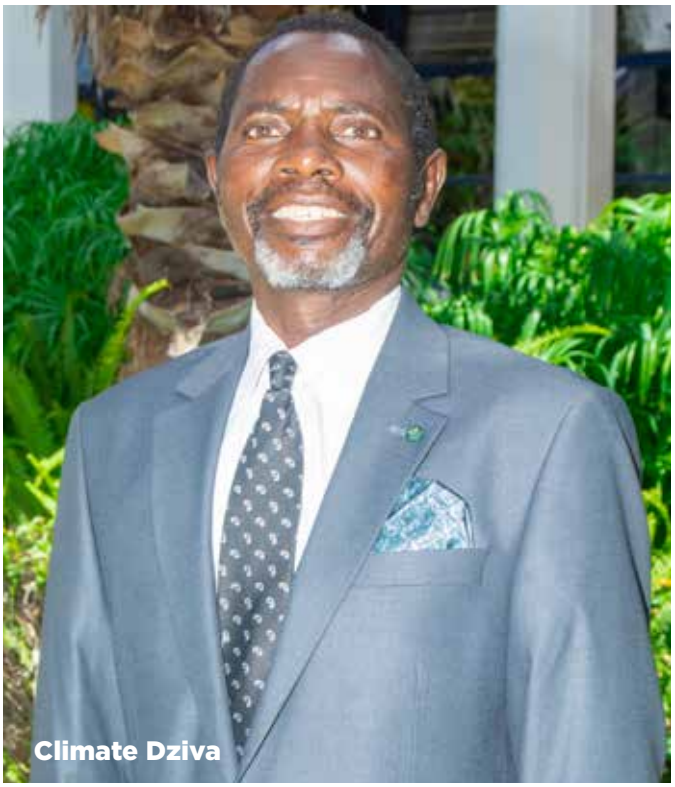
TWENTY-FIVE (25) YEARS
1. Tinashe A. Gonho
2. Munakandafa Mutasa
3. Reginald J. Masunda
4. Eunice Muzhanye
5. Bertha Chingwe
6. Climate Dziva
7. Ruka Maningi
8. Phillah Dziva
9. Francisca Chimbidze

Congratulations Makorokoto Amhlophe

MICROBIOLOGY LABORATORY

RJ Masunda experience as an MCAZ Employee for the past 25years (1998 to 2022)

RJ Masunda joined MCAZ in 1998 from the then Zimbabwe Regional Drugs Control Laboratory as a junior analyst in the Chemistry Laboratory. His key duties involved chemical analysis of pharmaceutical preparations and allied substances and procurement of all laboratory requirements. RJ Masunda was laterally transferred from the Chemistry laboratory to the Microbiology laboratory in 2007, after massive staff exodus for greener pastures. His key duties involved microbiological analysis of pharmaceutical preparations and allied substances, procurement of all laboratory requirements and training of laboratory staff. RJ Masunda actively participated in assistance with technical expertise from 2009 onwards, in the remodeling of the new Microbiology laboratory and procurement of laboratory equipment and related items as the laboratory gears towards WHO Prequalification, in the very near future. He has received numerous trainings, both inhouse and international to further sharpen his laboratory technical prowess. RJ Masunda has been granted opportunities with MCAZ management to further his career studies and has attained two degrees qualifications to date. His motto to duty is keep on learning everyday!!. The attained twenty five years at MCAZ by RJ Masunda appears to him like a decade because of his dual exposure to the two different MCAZ laboratories, where he has gained outstanding laboratory experience. RJ Masunda is truly grateful to MCAZ management for its great care towards him. Long live MCAZ. Thank you!!


Climate Dziva

I would like to give thanks to the Authority for the opportunity to serve for 25 years that I have been here. I do not speak as someone who gave the best always that's for the Authority to measure but one thing, I do is give my best at work. I am grateful as the Authority sent me for further training at UZ Medical School, National Archives, and Speciss College for Librarianship and Filing Courses. One can lose money, but one can never lose the knowledge they would have gained. The Authority gave me that opportunity. I want to thank all the colleagues that I have worked with over the years. I am here because of their contributions.

Long Service Awards





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25th ANNIVERSARY

MCAZ 25th ANNIVERSARY 1997 2022

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We wish you a success ahead

Happy Anniversary

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1997 25 ANNIVERSARY 2022

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Zimbabwe Red Cross Clinic

Congratulations MCAZ on your 25th anniversary you indeed maintained the mandate Protecting the right to quality medicines and medical devices.

Your tenacity, labour and teamwork is resounding as a medical regulatory Authority within the region and is far reaching leading by example.

Red Cross Pharmacy as part of Zimbabwe Red Cross Society Clinic whose fundamentals, principles and values are rooted in serving humanity recognize and appreciate the Authority's presence and growth. We commend you for the high standards and work ethic....**FROM ONE GIANT TO ANOTHER.**

MCAZ
Medicines Control Authority of Zimbabwe

A BIG CONGRATULATIONS TO THE AUTHORITY ON REACHING THIS MILESTONE. SCOVILLE PHARMACY WISHES YOU A HAPPY 25TH ANNIVERSARY

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