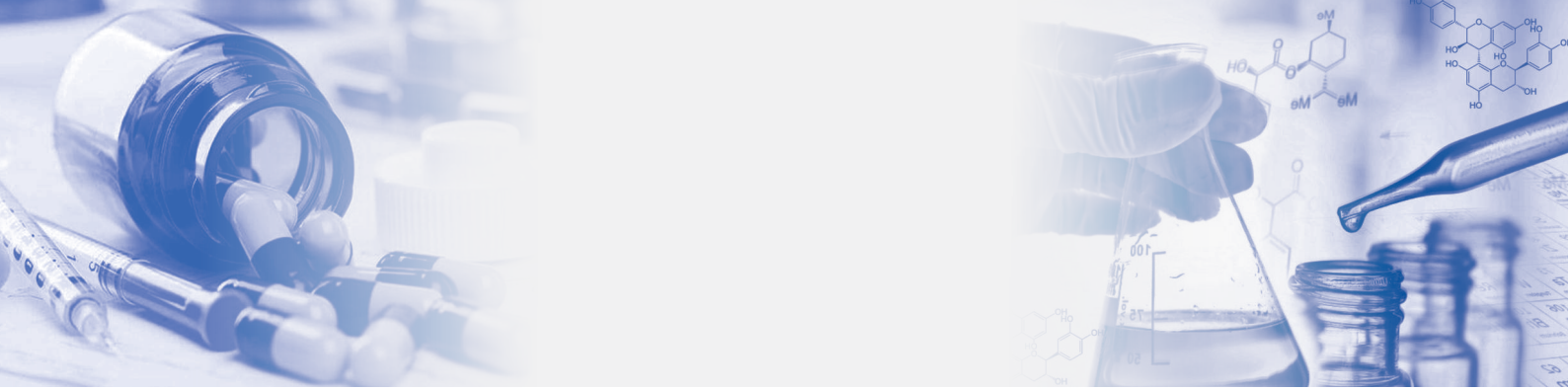
MCAZ

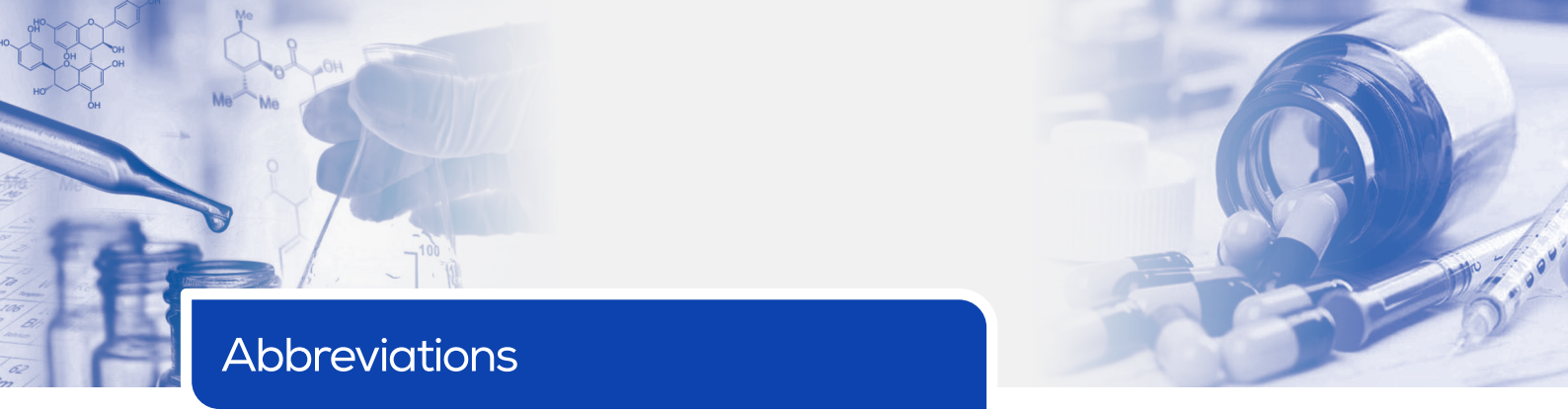
Medicines Control Authority of Zimbabwe

2019

ANNUAL REPORT

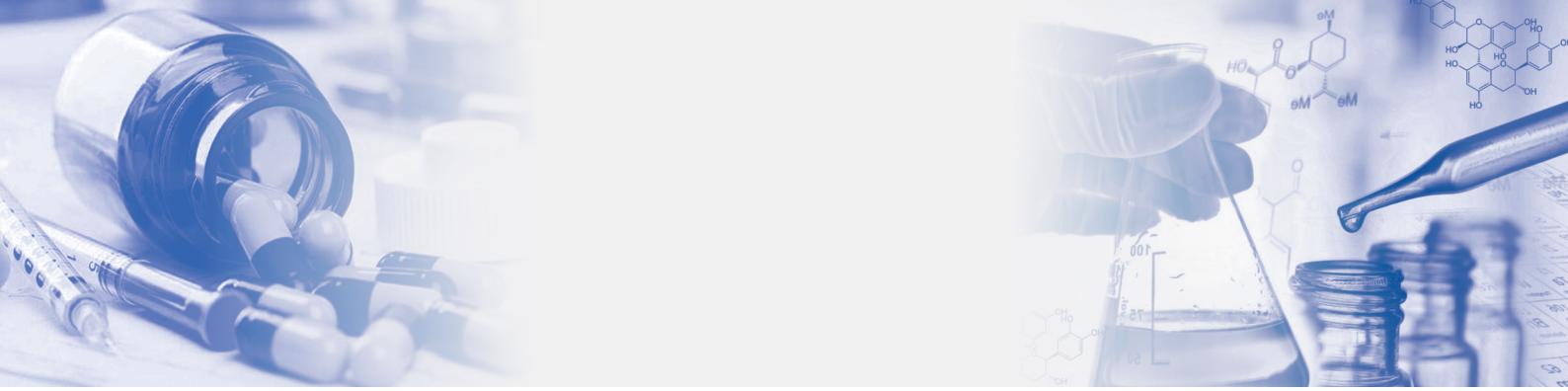
Contents



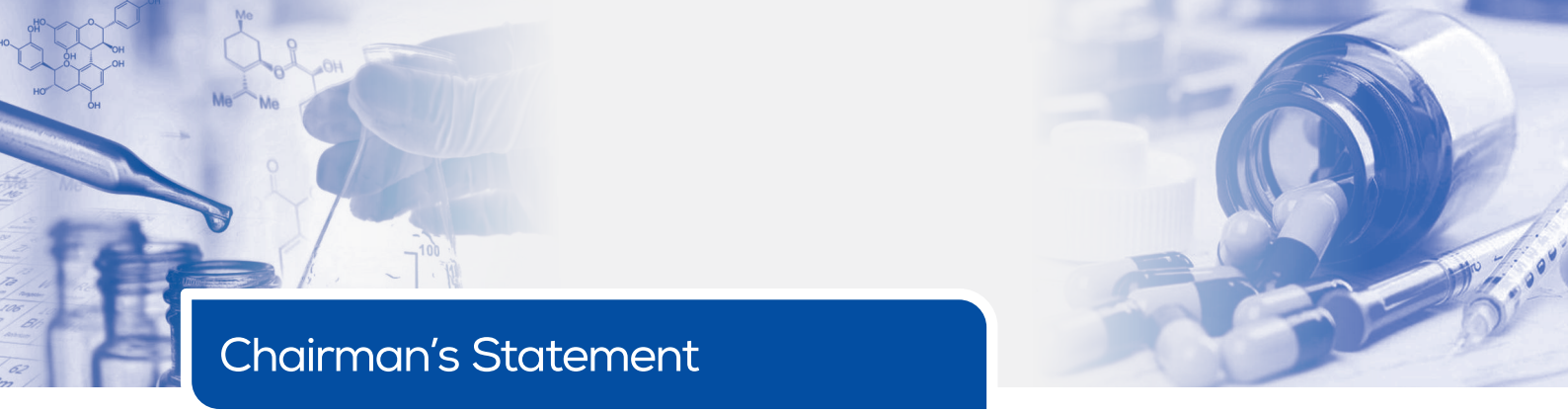


Abbreviations

ADR	Adverse drug reactions
AEFI	Adverse events following immunizations
AHIC	Animal Health Industry Committee
AHF	Aids Healthcare Foundation
AIDS	Acquired Immune-Deficiency Syndrome
ARV	Anti-retroviral
ART	Anti-retroviral Therapy
AVAREF	African Vaccine Regulatory Forum
bOPV	Bivalent Oral Polio Vaccine
CEO	Chief Executive Officer
CGF	Corporate Governance Framework
cGMPs	current Good Manufacturing Practices
CTD	Common Technical Document
DDT	DichloroDiphenylTrichloroethane
EMA	European Medicines Agency
EPI	Expanded Programme on Immunization
ERM	Enterprise Risk Management
EVR	Evaluations and Registration
FHI	Family Health International
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
GRC	Governance, Risk management and Control
HDF	Health Development Fund
HPFB	Health Products and Food Branch
HPLCs	High Performance Liquid Chromatography
HTF	Health Transition Fund
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSR	Individual case safety reports
ICT	Information and communications technology
IEC	International Electrotechnical Commission
IFRS	International Financial Reporting Standards
ISO	International Organization for Standardization
KRA	Key Result Area
MASCA	Medicines and Allied Substance Control Act Chapter (15.03)
MCAZ	Medicines Control Authority of Zimbabwe
MDU	Medical Devices Unit
MoHCC	Ministry of Health and Child Care
NEPAD	New Partnership for Africa's Development
NFM	New Funding Model
NMRAs	National Medicines Regulatory Authorities
NOMCoL	Network of Official Medicines Control Laboratories
OIE	Organisation Internationale de Epizooties



PECOGO	Public Entities Corporate Governance Act
PFMA	Public Finance Management Act
PIM	Pharmacist Initiated Medicines
PMS	Post Market Surveillance
PP	Prescription Preparations
PQ	Prequalification Programme
PSI-Zim	Population Services International- Zimbabwe
PSZ	Pharmaceutical Society of Zimbabwe
PVCT	Pharmacovigilance and Clinical Trials
QMS	Quality Management System
RCORE	Regional Centre of Regulatory Excellence
SADC	Southern African Development Community
SADCAS	Southern Africa Development Community Accreditation Service
SAEs	Serious Adverse Even
SANAS	South African National Accreditation System
SSFFC	Substandard/Spurious/Falsified/Falsely-labelled/Counterfeits
TB	Tuberculosis
tOPV	Trivalent Oral Polio Vaccine
TSR	Targeted Spontaneous Reports
UNDP	United Nations Development Programme
USP	United States Pharmacopeia
VAT	Value-Added Tax
ZEPI	Zimbabwe Expanded Programme on Immunization
ZIMRA	Zimbabwe Revenue Authority
ZNFPC	Zimbabwe National Family Planning Council
ZIMCODE	National Code on Corporate Governance for Zimbabwe
ZNFPC	Zimbabwe National Family Planning Council



Chairman's Statement

The year 2019 was the first year of our three year strategy in which our key focus was continued engagement with our stakeholders and attainment of WHO listed authority status among other things. The new strategy brought with it a renewed commitment by the Authority to comply with the Public Enterprises Corporate Governance Act (PECOGO) requirements. This resulted in the review of the Authority's operations focusing on frequency of Committee meetings and term limits.

The Authority continued to fulfil its mandate to protect public and animal health through the work of its various Committees. Of note, are the following pieces of legislation that were drafted by the Legal Committee to enable the Authority to effectively execute its mandate, Medicines and Allied Substances Control (Veterinary medicines) regulations. The Dangerous Drug regulations were also reviewed to be responsive to the changes in dispensing practitioners in the palliative care sector.

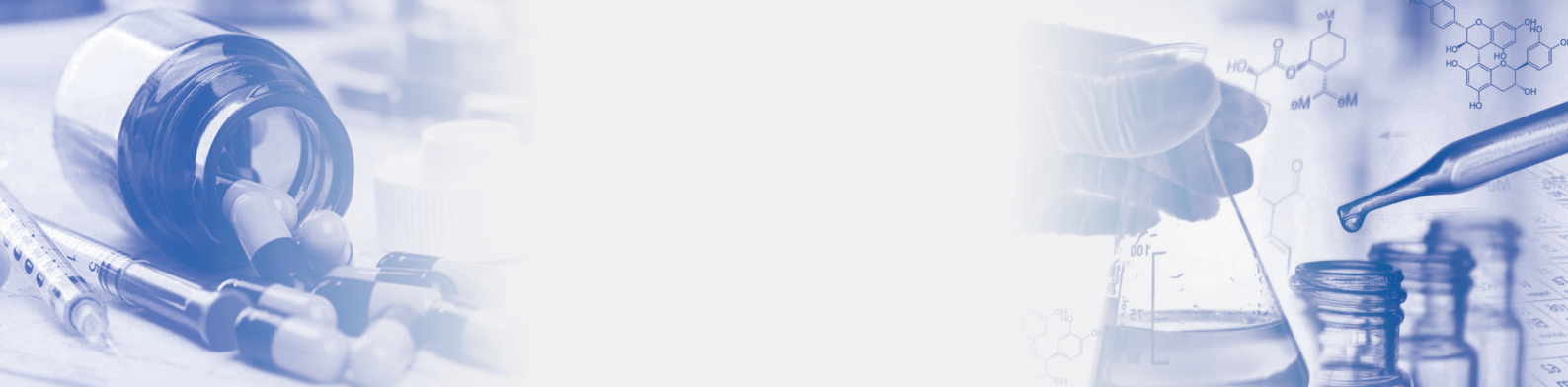
One of the Authority's responsibilities is to ensure that people handling medicines comply with the requirements of the Medicines and Allied Substances Control Act (MASCA) including provision of these medicines from approved premises. The Authority noted with concern that unregistered medicines were being sold to the unsuspecting public illegally. As a result, the Authority stepped up its engagement with the Zimbabwe Republic Police Criminal Investigation Department (CID) Drugs and Narcotics sector as well as public awareness campaigns through the Enforcement and Public Relations units. The Hearing Committee was regrettably kept busy dealing with errant professionals contravening MASCA. The incidents of lack of compliance by practitioners was another cause of concern for the Authority.

The Chemistry and Medical Devices laboratories were able to maintain accreditation to ISO 17025, whilst the entire organisation was certified to ISO 9000:2015. The Authority is proud to be able to provide laboratory services to stakeholders locally and beyond our borders.

The process of registering medicines ensures that the medicines are produced in line with the required quality standards. This gives assurance to the public of the quality, safety and efficacy of medicines. While it is important to ensure that standards are met, a balance always needs to be struck with the time taken to register the medicines. Protracted review and registration times are undesirable as this can hinder access to medicines by patients and achieving this balance is of great priority to the Authority. The Authority continued to practise reliance and abridge the review of medicines already approved by trusted authorities to facilitate faster access to the medicines. The decision by the Authority to prioritise registration of locally manufactured medicines resulted in a steady decline in the time to registration from 2017 to 2019. It is my hope and expectation that the time taken to register medicines will continue to go down.

The Authority's continued engagement with the local pharmaceutical industry through the development and monitoring of Good Manufacturing Practice (GMP) roadmaps for manufacturers and trainings offered to both industry and regulators through the MCAZ regional centre of regulatory excellence (RCORE) and quality circles. A highlight for 2019 was the approval of a local site to manufacture complementary medicines.

The Pharmacovigilance and Clinical Trials (PVCT) Committee was faced with the challenge of reviewing safety alerts issued by other regulatory authorities globally to determine their applicability for the Zimbabwean population. Where necessary safety alerts were then issued to the medical profession. As the National Pharmacovigilance Centre, the PVCT Committee also reviewed adverse



drug reaction reports submitted by the public and health professionals although the reporting rate can still be improved.

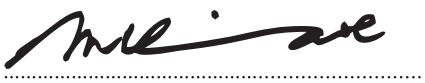
I wish to thank all the Committees providing oversight to our technical divisions as well as the Human Resources, Audit, ICT, Finance Quality and Resource Mobilisation units whose work ensured a smooth flow of the Authority's business and compliance with various local and international standards including the PECOGA requirements. I am pleased that the MCAZ continues to embrace technology and work on automation of its processes for the convenience of our stakeholders.

Challenges faced in the reporting year were the somewhat sluggish revenue inflows compared to previous years which negatively impacted the Authority's resource base as well as loss of experienced staff to newly established regulatory authorities in the region. The Authority once again had to hire new staff who have to undergo intensive training to plug the expertise gaps. Despite the challenges in the larger macro-economic environment, the Authority managed to maintain international partnerships / collaborations and implement the various projects, for example, the SADC Medicines Registration Harmonisation project and European and Developing Countries Clinical Trials Partnership (EDCTP) regulatory sciences project for which the MCAZ is the implementing and coordinating agency respectively.

As part of its corporate social responsibility, the MCAZ continued to sponsor pharmacy students at the University of Zimbabwe and Harare Institute of Technology under the MCAZ and Dr Emilio Mazhindu Scholarship.

Overall, the Authority managed to achieve its goals and execute its mandate in spite of the challenges of the operating environment. On behalf of the Board, I wish to thank our parent Ministry, our various stakeholders, our expert Committees, management and staff of the MCAZ for your hard work and single-minded determination to achieve our vision to be an effective medicines regulator in Zimbabwe and a leading regulatory authority in the world.

M. CHIWARE (DR)



BOARD CHAIRMAN

Director General's Statement

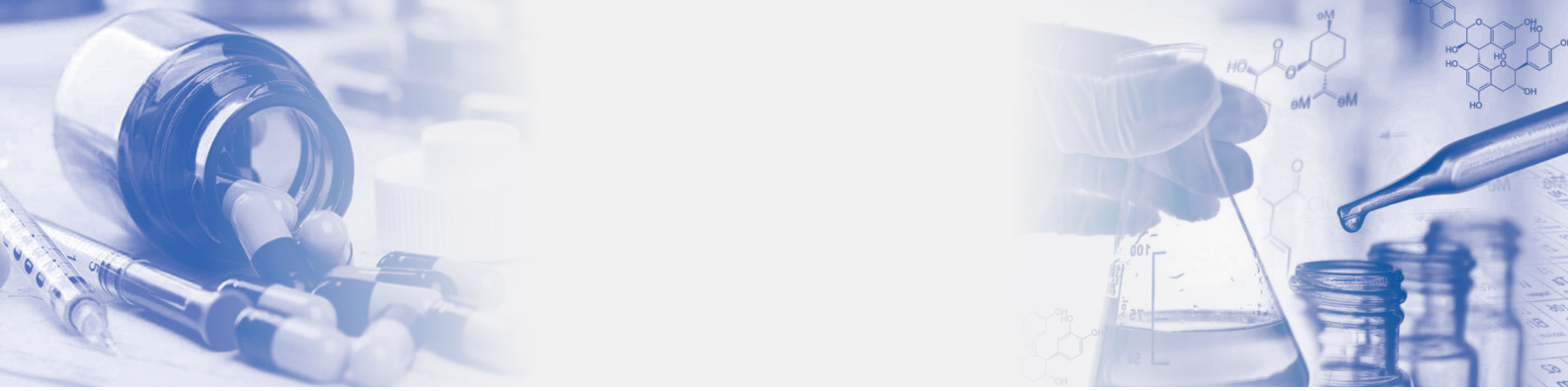
The 2019 – 2022 strategic plan was launched following the successful implementation of the previous one. It is my pleasure to report to you the Authority's performance against strategic goals for the year 2019 including challenges faced and how the Authority navigated these.

The Authority's workforce is one of its greatest assets and it is of utmost importance to us to ensure that we have competent and motivated staff. To achieve this, we invested in a leadership development program for our management, internal and external trainings for staff, team building activities and internal customer satisfaction surveys to build skills and competences as well as to identify any issues requiring attention. The result of this investment was seen in the increased work output, team cohesion and high level of individual performance recorded. A challenge however, that was faced in 2019 was attrition of highly skilled staff in pursuit of opportunities in neighbouring countries in the SADC region. Although the Authority has hired people to fill the vacancies, it will take some time before the impact is felt due to the steep learning curve of some of the jobs.

A sustainable resource base is essential for business continuity and enables the Authority to perform its mandate. The year under review was a challenging year financially as revenue declined on the back of monetary policy changes. The Authority fees were not keeping pace with the rate of inflation. The Authority endeavoured to cushion its stakeholders from the effects of hyperinflation by maintaining the fees as they were for as long as was possible trusting that this would in some way contribute to keeping medication affordable for the Zimbabwean public.

The MCAZ achieved a huge milestone when the quality management system was certified to be in compliance with the ISO 9001:2015 standard by the Standards Association of Zimbabwe. This standard is designed to help organizations meet and exceed their customer's requirements and expectations. This is the essence of the MCAZ's values which are customer-focus, integrity, accountability and continuous improvement. An area of interest to our customers is effective regulatory processes and automated systems. The divisions and units developed a tool for tracking key process timelines and these were monitored through the Quality Management Review Meetings. We plan in future to publish these timelines on our website and strictly adhere to them in line with good regulatory practices. Automation of the Authority's processes and systems is now at 75% efficiency and this should result in a much improved customer experience. The goal of course is to reach 100% in the coming year.

The Authority administered the annual customer satisfaction survey in line with our customer engagement plan. The response rate was encouraging and the divisions are working on addressing shortcomings identified in the survey. The MCAZ appeared in various media and visited schools, shows and a number of expos to increase awareness of medicine use and the role of the regulator.

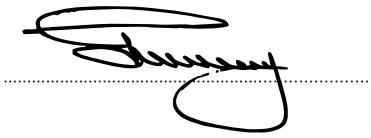


The highlight of our year was the successful hosting of the 4th Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA 2019) by the MCAZ in partnership with Ministry of Health and Child Care, African Union Development Agency (AUDA NEPAD), SADC and WHO. The conference attracted participants from over 37 countries and we were proud to showcase the beauty of the mighty Victoria Falls and the hospitality of the Zimbabwean people.

I am proud that the MCAZ was able to record successes and navigate the challenges that presented along the way. Guided by our strategy, we remained resolute in achieving our mission. I am immensely grateful to the Ministry of Health and Child Care, the MCAZ Board, expert Committees, management, members of staff and our stakeholders for their support and hard work. Thank you.

As we enter 2020, which will be my last year as Director General of the MCAZ, it is my hope that we can maintain the MCAZ as the formidable organisation that it is, in the country and on the world stage. It has been my privilege to lead the organisation for the past few years.

G. N. MAHLANGU (MS)



MCAZ DIRECTOR-GENERAL

Governance and Risk Report

The Authority believes that corporate governance is core to ensuring the creation, protection, and enhancement of stakeholder value. Our stakeholders include the Government of Zimbabwe, the Ministry of Health and Child Welfare, other government institutions, the pharmaceutical industry, customers, our suppliers, and the public at large. The Authority is cognizant that for governance to act as an enabler in business, continuous monitoring of the governance structure is imperative to ensure the optimum process flows and to prevent any possible transgressions in the organization. According to this, the Authority is managed within a framework of accountability to achieve its strategic objectives with the maximum level of effectiveness and efficiency to attain, among other things:

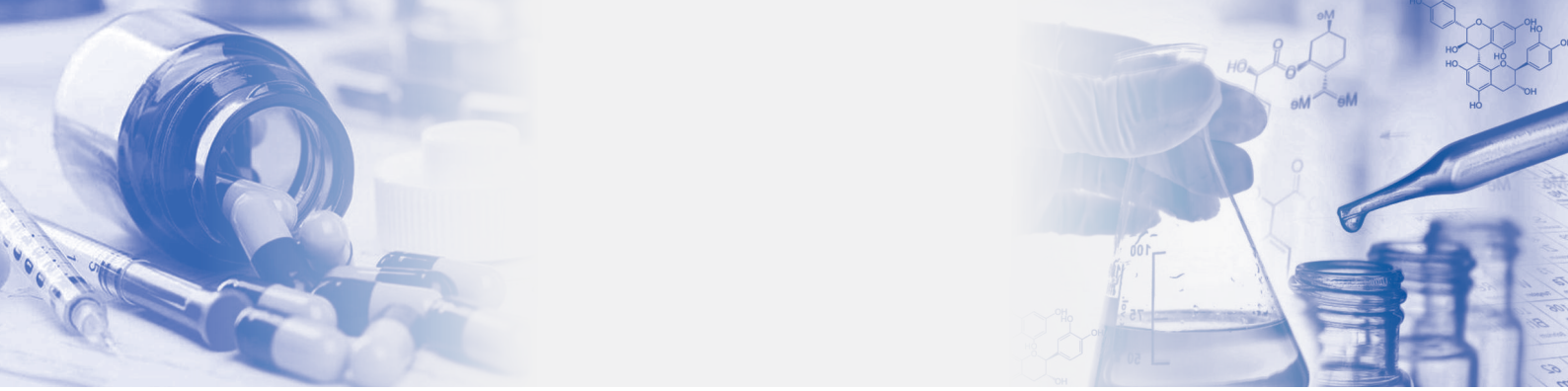
- The fulfillment of the Authority's primary mission ***(To protect public and animal health by ensuring that accessible medicines and allied substances and medical devices are safe, effective, and of good quality, through enforcement of adherence to standards by manufacturers and distributors).***
- Accountable, effective and efficient utilization of powers, decision making, organizational structures, and monitoring and control measures;
- Maintenance of sound and transparent relations with the Authority's stakeholders; ·
- Compliance with all applicable legal and regulatory requirements in terms of which the Authority carries out its activities; and
- Acknowledgement of the needs of the community and the environment in terms of the physical effects of the Authority's operations on its surroundings and its interaction with the general public (Corporate Social Responsibility).

The Board of Directors

The Board is responsible for setting and reviewing the strategic direction of the Authority, implementation of that strategy by Management, overall conduct of the Authority's business including overseeing its governance, risk management, and control frameworks. As part of its mandate, the Board continues to give importance to the principles of transparency, integrity, and accountability under the requirements set out by the MASCA and other laws, regulations, standards, and best practices among others:

- Public Entities Corporate Governance Act (PECOGO)
- Public Finance Management (PFMA) Act Chapter (22.19)
- National Code on Corporate Governance for Zimbabwe (ZIMCODE)
- Corporate Governance Framework (CGF) for State Enterprises and Parastatals and
- International Financial Reporting Standards (IFRS).

During 2019 the Board comprised of ten (10) members with diverse skills and expertise as required by section 4 of the Medicines and Allied Substance Control Act (MASCA) [Chapter15.03]. In line with good governance and as provided for in MASCA, various committees were established and delegated with certain functions and responsibilities to assist the Board in the discharge of its duties.

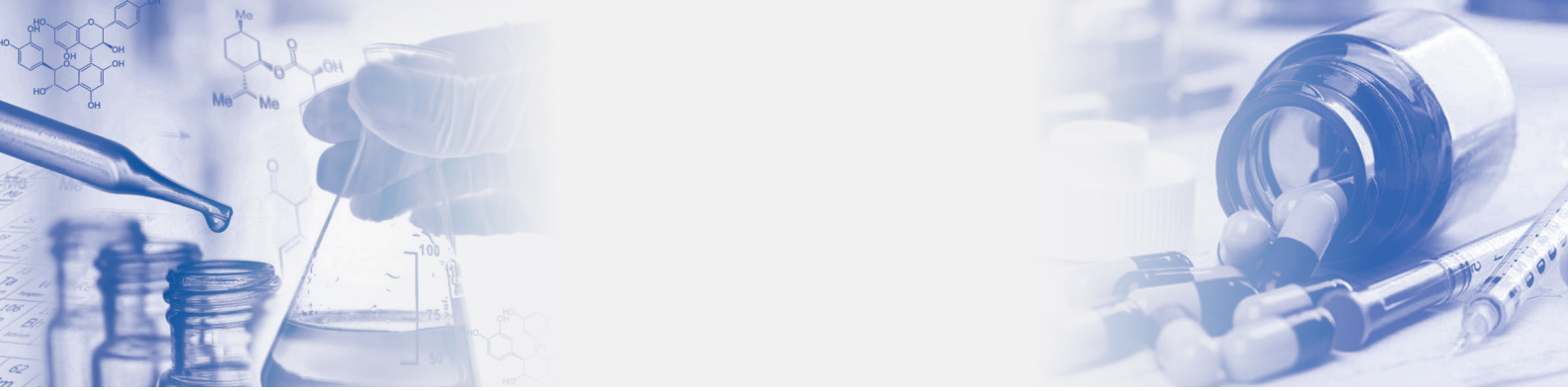


	Board and Committee Attendance (From 1 January 2019 to 31 December 2019)							
	Board		Audit Committee		Human Resources Committee		Finance Committee	
	Attended	Possible	Attended	Possible	Attended	Possible	Attended	Possible
Dr M Chiware	4	4					4	4
Dr AF Zinanga							4	4
Mr J Chidora	3	4			6	6		
Dr C Duri	4	4						
Mrs R Hove	3	4						
Mr J Kunonga	4	4	6	6	6	6		
Dr C Mutisi	3	4	6	6				
Dr S Mutambu	3	4						
Dr C Pasi	4	4						
Mrs N Samuriwo	3	4						
Ms Y M Zhou	3	4					3	4
Mrs F Chinogurei					4	6		
Mr E Jinda					4	6		
Dr P Muvavarirwa					3	6		
Mrs J Ncube					6	6		
Mr C D Mahofa			5	6				
Ms G Zvaravanhu			1	6				
Ms N G Maphosa			6	6				
Dr I Ruzengwe							3	4
Mr C Shonhiwa							3	4

The Management Team

Below is the Management team for 2019. Management team is accountable to the Board. To allow the Board to effectively discharge its duties, Management and staff are required to provide periodic updates and respond to queries that the Board may have on the operations and planning of the organization.

Name	Position
Ms G.N Mahlangu	Director-General
Dr W. Wekwete	Head, Evaluations and Registrations
Mr R. Rukwata	Head, Licensing and Enforcement
Mrs P.P Nyambayo	Head, Pharmacovigilance and Clinical Trials
Mrs B. Dube	Head, Chemistry
Mr E. Kulube	Head, Finance
Mr T. Munhenga	Head, Human Resources
Mrs A. Chikowore	Quality Manager
Mr T. Gonho	Manager, Microbiology and Medical Devices



Name	Position
Mr M. Mutizira	Internal Auditor
Mr T. Nyovhi	ICT Manager
Mrs R. Gwata	Finance Manager
Mr F. Tembo	Procurement and Administration Manager
Mrs C. Samatanga	Chief Regulatory Officer, LED
Ms A. Verenga	Chief Regulatory Officer, LED
Mrs T. Makamure - Sithole	Chief Regulatory Officer, EVR
Mr C. Shamuyarira	Chief Analyst, Chemistry

Enterprise Risk Management

The Authority has always had a strong focus on risk management and has adopted a structured enterprise-wide approach to managing risk through the Enterprise Risk Management (ERM) framework. Responsibility and accountability for risk management resides at all levels within the Authority. The primary responsibility for risk management resides with functional Heads, where the process of assessing, evaluating, measuring and mitigating risk is ongoing and integrated into the day to day activities of the unit/division. Quality unit monitors 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. The Audit Committee reviews the effectiveness of the framework and also brings the high risks to the attention of the Board in compliance with the ERM framework.

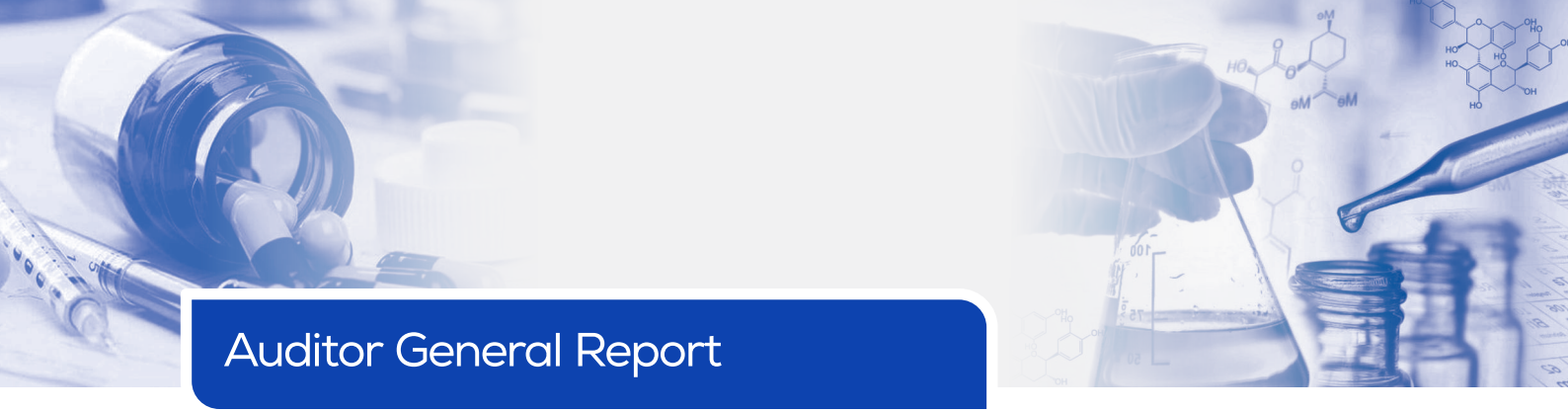
Deloitte Tip Offs Anonymous

The Authority is committed to high standards of openness, probity and accountability and recognises that our stakeholders need to have confidence in those that are responsible for the delivery of services. Pursuant to this, the Authority subscribes to Deloitte's Tip Off Anonymous Service, a platform used for reporting fraud, corruption, dishonesty, harassment, conflict of interest and any other unethical behaviour in the workplace.

Internal Audit

Public Entities Corporate Governance Act (PECOGO) highlights the need for entities to maintain good systems of internal control to manage the risks the company faces. Internal Audit plays a key role in providing assurance on internal controls, risk management and governance processes in accordance with the Institute of Internal Auditor's (IIA) International Standards for the Professional Practice of Internal Auditing.

During 2019 financial year, the unit issued eight reports related to various engagements, and the results of our work were communicated to the Authority through the Audit Committee and to Management. We also performed follow-up work during the year to monitor whether Management's plans of action have been effectively implemented. Status reports of outstanding audit findings and recommendations were issued quarterly to Management and the Audit Committee.



Auditor General Report

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 FOR THE MEDICINES CONTROL AUTHORITY OF ZIMBABWE FOR THE YEAR ENDED DECEMBER 31, 2019

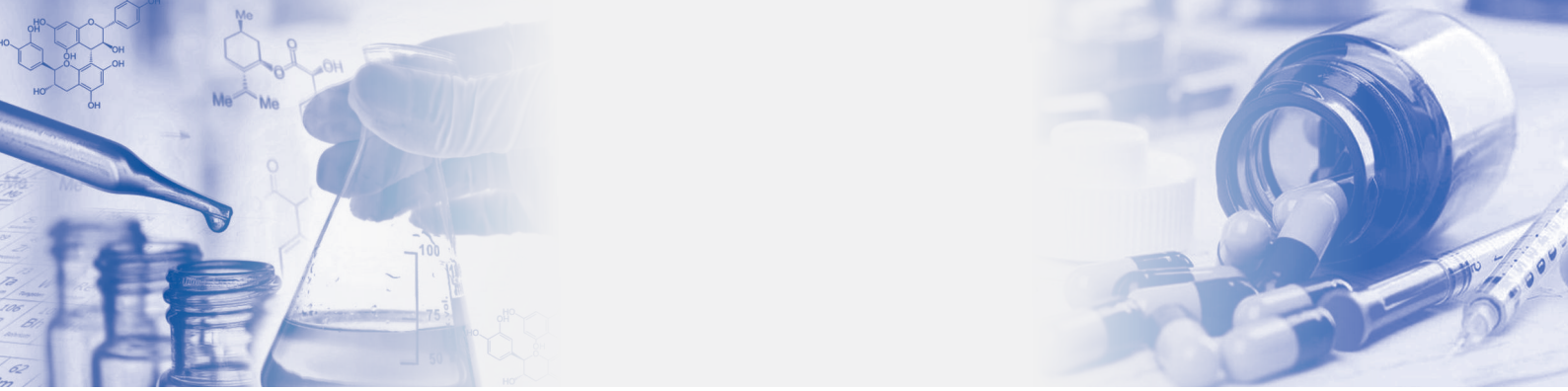
Report on the Audit of the Financial Statements
Adverse Opinion on the Consolidated Financial Statements
I have audited the consolidated financial statements of the Medicines Control Authority of Zimbabwe and its subsidiary ("the Group") as set out on pages 7 to 28, which comprise the consolidated statement of financial position as at December 31, 2019, 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 consolidated financial statements, including a summary of significant accounting policies and other explanatory information.

In my opinion, because of the significance of the matters discussed in the Basis for Adverse Opinion paragraph of my report, the accompanying consolidated financial statements do not present fairly the consolidated financial position of the Group as at December 31, 2019, its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRSs).

Adverse Opinion on the Authority's financial statements
In my opinion, because of the significance of the matter discussed in the Basis for Adverse Opinion paragraph of my report, the accompanying financial statements do not present fairly the financial position of Medicines Control Authority of Zimbabwe as at December 31, 2019, its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRSs).

Basis for Adverse Opinion for the Group and the Authority
The Group and the Authority translated its comparative financial statements and transactions for the period up to February 22, 2019 using an exchange rate of 1:1 for US$ to ZW$ Dollar as prescribed to entities through SI 33/2019. In order to comply with Statutory Instrument 33 of 2019, issued on February 22, 2019, the Group and the Authority changed their functional currency with effect from this date. Although the rate was legally pegged at 1:1, multiple pricing practices and other transactions observed and reported publicly indicated exchange rates other than 1:1 between ZW$ and US$ amounts. The exchange rates applied meet the legal requirements, but however did not meet the criteria for appropriate exchange rates in terms of International Financial Reporting Standard (IFRSs) 21 " The effect of changes in foreign exchange" as defined in IAS 21. The financial statements of the Group and the Authority include balances and transactions denominated in USD that were not converted to ZW$ at an exchange rate that reflects the economic substance of its values required by International Financial Reporting Standards (IFRS) IAS 21, which requires entities to use an appropriate exchange rate.

The official interbank exchange rate came into existence, through Exchange Control Directive RU 28 of 2019 issued by the RBZ in February 2019 and was initially pegged at a starting rate of 2.5. Transactions and balances from February 22, 2019 were now translated using the interbank rates.



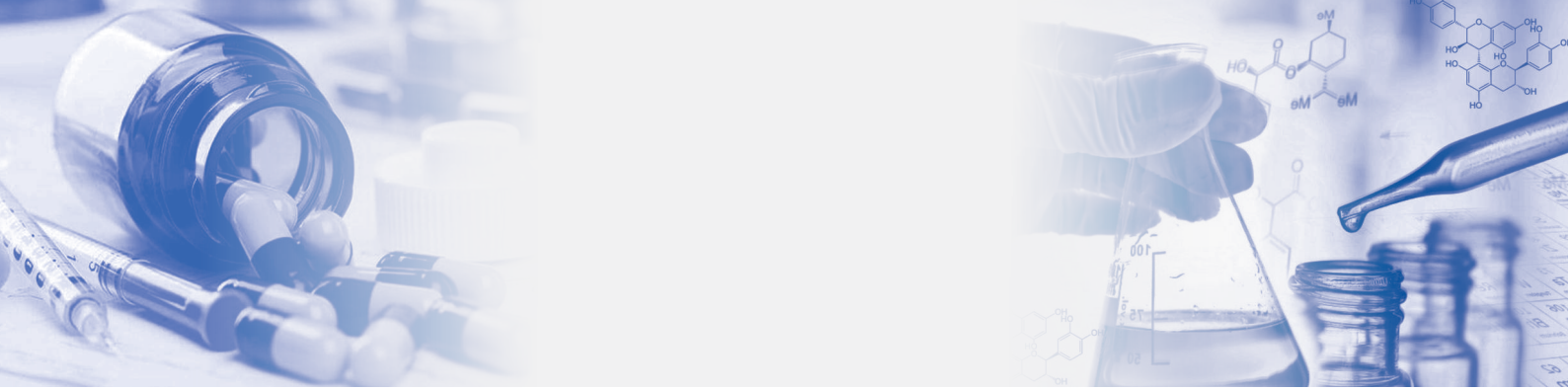
No assessment was carried out to show appropriateness of the interbank rate to the existing economic environment. The interbank rate does not represent the price that can be received for foreign currency as many were unable to access foreign currency through the interbank market. As a result, the impact of the Group and the Authority's inability to comply with IAS 21 on the financial statements had been considered material and pervasive to the financial statements as a whole. Had the Group and the Authority applied the requirements of IAS 21, many elements of the accompanying consolidated financial statements would have been materially adjusted. The financial effects on the inflation adjusted financial statements of this departure have not been determined.

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.

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, 2019. These matters were addressed in the context of my audit of the Medicines Control Authority of Zimbabwe consolidated financial statements as a whole, and in forming my opinion thereon, and I do not provide a separate opinion on these matters.

Key Audit Matter	How my audit addressed the Key Audit Matter
Valuation and impairment of property, plant and equipment estimated useful life. Refer to notes 2.6.1, 3.1 and 4 of the consolidated financial statements The Group held property, plant and equipment with revalued carrying amount of ZW$ 74 044 636 as at December 31, 2019. The assets were revalued in accordance with IAS 16. Property, plant and equipment was revalued using an expert. This revaluation process involves significant judgments in determining the fair value 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 the valuation of property, plant and equipment included: • Tested the independence and expertise of the valuer used to determine the revalued amounts. • Critically evaluated the methodology and assumptions used by the valuer when performing the valuation. • Inspected documentary evidence of the state of property, plant and equipment. Based on evidence gathered, I found the expert's assumptions in relation to useful lives and the revalued carrying amounts of property, plant and equipment reasonable.
Revenue recognition, refer to notes 13, 14 and 3.5 of the consolidated financial statements. The Group's revenue amounted to ZW$ 154 704 401 for the year ended December 31,	My audit procedures to address the risk of material misstatement relating to revenue included: • Tested the system (internal control)



Key Audit Matter	How my audit addressed the Key Audit Matter
2019. Revenue is predominantly derived from medicines control income and laboratory income. Revenue recognition is highly complex due to the large number of service offerings and high volumes of transactions. As a result, recognition of revenue was considered to be a key audit matter.	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.

Other Information in the Annual Report

The Directors are responsible for the other Information. The other Information comprises all the information in the Medicines Control Authority of Zimbabwe's 2019 annual report other than the financial statements and my auditor's report thereon ("the other Information").

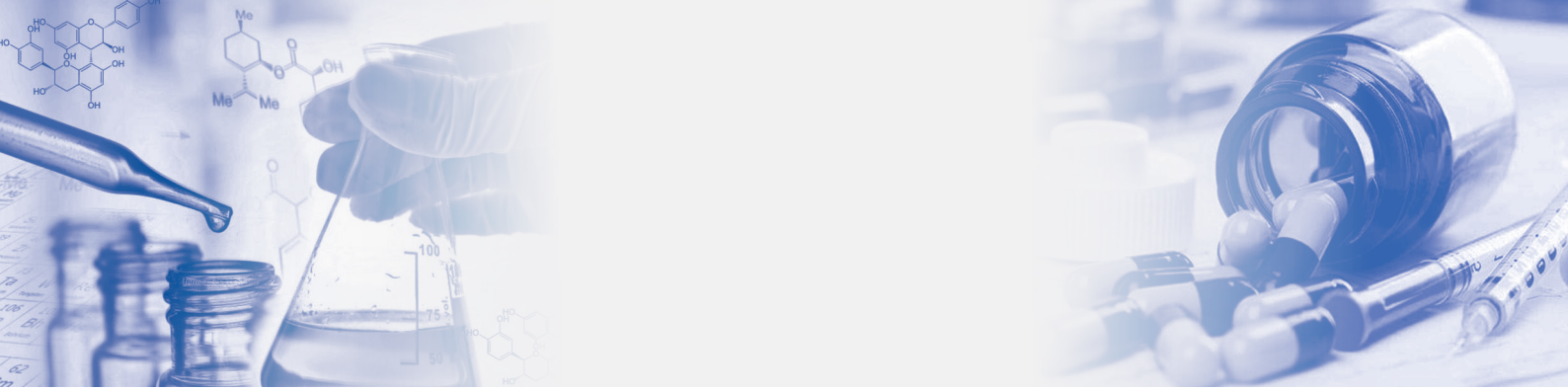
My opinion on the consolidated financial statements does not cover the other Information and I do not express any form of assurance or conclusion thereon.

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

The Authority's management and those charged with governance are responsible for the preparation and fair presentation of these financial statements in accordance with International Financial Reporting Standards (IFRS) 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 Authority'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 Authority or to cease operations, or has no realistic alternative but to do so.
Those charged with governance are responsible for overseeing the Authority's financial reporting process.



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

My objectives 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 is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

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

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

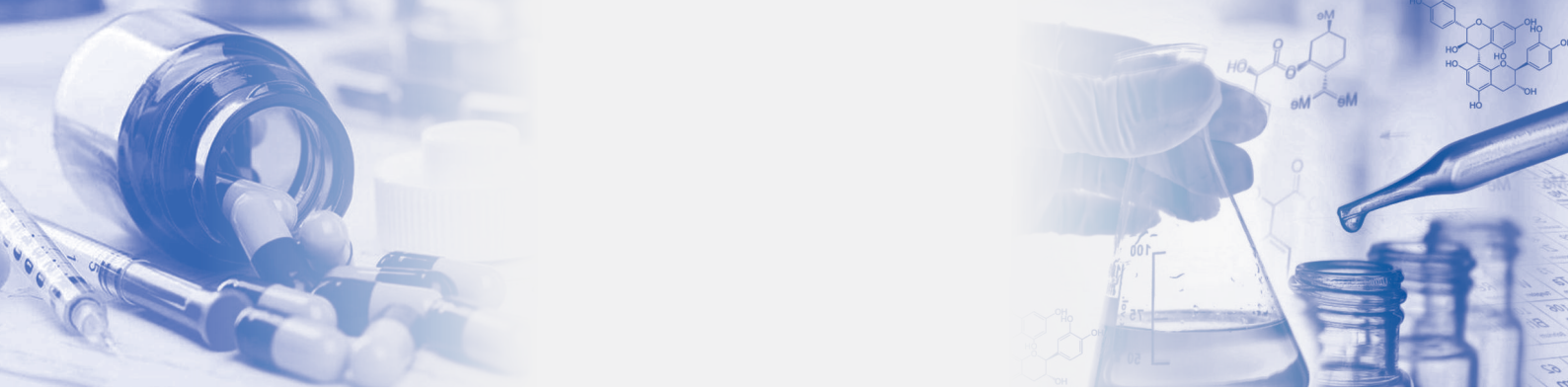
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control.

- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.

- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to the events or conditions that may cast significant doubt on the Authority'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 consolidated 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 Authority to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

- Conclude on the appropriateness of the directors' 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 Authority'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 the auditor's report. However, future events or conditions may cause the Authority to cease to continue as a going concern;



I communicate with directors 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 provide directors with 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 directors, 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.

Other Report on Other Legal and Regulatory Requirements

In my opinion, the financial statements 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.

November 17, 2020.

M. CHIRI (MRS),
AUDITOR – GENERAL.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT DECEMBER 31, 2019

	Note	MCAZ GROUP			
		Inflation adjusted		Historical cost	
ASSETS		**2019 ZWL$**	**2018 ZWL$**	**2019 ZWL$**	**2018 ZWL$**
Non-current assets		**99,911,536**	**42,670,883**	**98,888,827**	**5,761,903**
Property, plant and equipment	4	74,044,636	32,483,676	73,021,927	4,121,903
Investment property	5	25,866,900	10,187,207	25,866,900	1,640,000
Investment in subsidiary	6	-	-	-	-
Current assets		**57,134,053**	**10,871,134**	**57,106,059**	**1,746,553**
Inventories	7	322,447	193,740	294,453	27,640
Trade and other receivables	8	2,954,837	3,936,916	2,954,837	633,789
Cash and cash equivalents	9	53,856,769	6,740,478	53,856,769	1,085,124
Total assets		157,045,589	53,542,017	155,994,886	7,508,456
RESERVES AND LIABILITIES					
Reserves		134,605,572	41,578,619	146,962,764	5,872,806
Capital reserve		52,682,803	52,682,803	5,444,017	5,444,017
Accumulated fund		40,198,895	(13,037,623)	71,407,173	(1,260,172)
Revaluation reserve		37,492,191	-	66,251,522	1,450,408
Non controlling interest		4,231,683	1,933,439	3,860,052	238,553
		-		-	
Non-current liabilities		16,194,294	4,217,104	2,786,399	388,603
Deferred income	10	16,172,710	4,178,033	2,784,226	382,312
Deferred tax	11	21,584	23,138	2,173	3,726
Staff vehicle contribution scheme		-	15,933	-	2,565
Current liabilities		**6,245,723**	**7,746,294**	**6,245,723**	**1,247,047**
Trade and other payables	12	6,082,043	6,619,688	6,082,043	1,065,679
Leave pay provision		163,680	1,126,606	163,680	181,368
Total reserve and liabilities		**157,045,589**	**53,542,017**	**155,994,886**	**7,508,456**

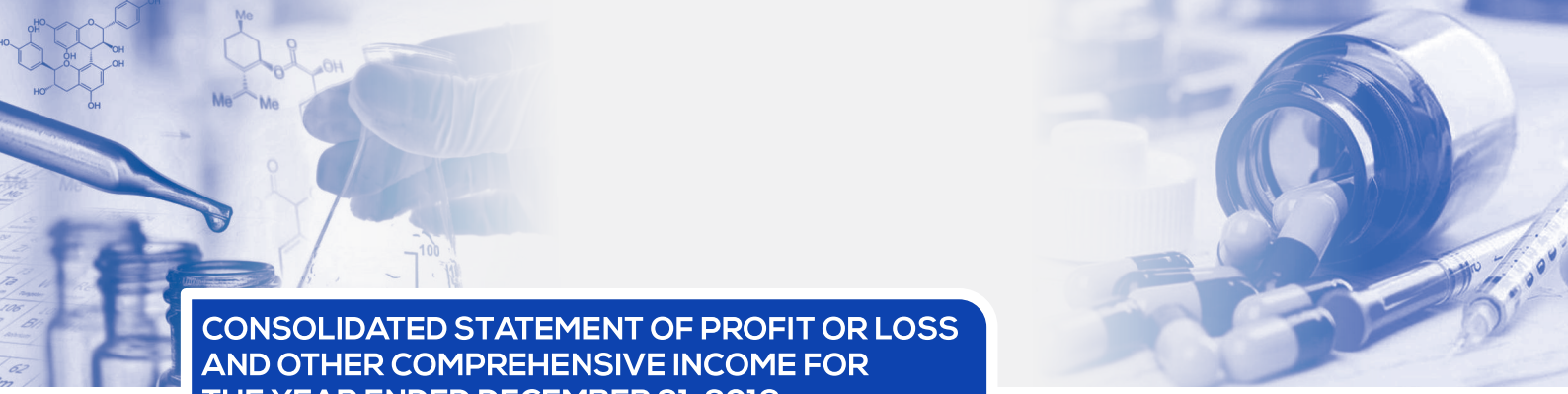
CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT DECEMBER 31, 2019 (Cont.)

		AUTHORITY			
	Note	Inflation adjusted		Historical cost	
ASSETS		**2019 ZWL$**	**2018 ZWL$**	**2019 ZWL$**	**2018 ZWL$**
Non-current assets		**94,507,555**	**40,311,770**	**89,828,513**	**5,413,316**
Property, plant and equipment	4	64,753,640	28,191,124	63,743,018	3,554,721
Investment property	5	25,866,900	10,187,207	25,866,900	1,640,000
Investment in subsidiary	6	3,887,015	1,933,439	218,595	218,595
Current assets		**57,126,234**	**10,722,205**	**57,098,240**	**1,722,577**
Inventories	7	322,447	193,740	294,453	27,640
Trade and other receivables	8	2,954,837	3,863,631	2,954,837	621,991
Cash and cash equivalents	9	53,848,950	6,664,834	53,848,950	1,072,946
Total assets		**151,633,789**	**51,033,975**	**146,926,753**	**7,135,893**
RESERVES AND LIABILITIES					
Reserves		**129,072,588**	**39,069,576**	**137,754,036**	**5,500,083**
Capital reserve		52,682,803	52,682,803	5,444,017	5,444,017
Accumulated fund		41,867,085	(13,613,227)	71,262,857	(1,341,242)
Revaluation reserve		34,522,700	-	61,047,162	1,397,308
Non controlling interest		-	-	-	-
		16,172,713	**4,193,966**	**2,784,226**	**384,877**
Deferred income	10	16,172,710	4,178,033	2,784,226	382,312
Deferred tax	11	-	-	-	-
Staff vehicle contribution scheme		-	15,933	-	2,565
Current liabilities		**6,388,491**	**7,770,433**	**6,388,491**	**1,250,933**
Trade and other payables	12	6,224,811	6,643,827	6,224,811	1,069,565
Leave pay provision		163,680	1,126,606	163,680	181,368
Total reserve and liabilities		**151,633,789**	**51,033,975**	**146,926,753**	**7,135,893**

E. Kulube
Head Finance

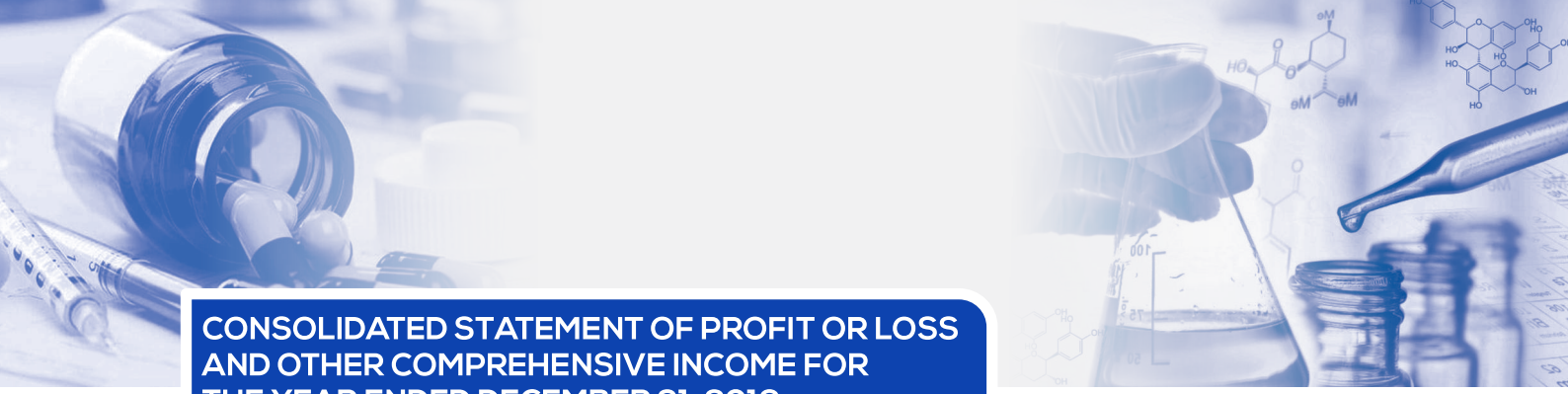
M. Chiware
Authority Chairperson

G.N. Mahlangu
Director General



CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED DECEMBER 31, 2019

	Note	MCAZ GROUP			
		Inflation adjusted		Historical cost	
		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
INCOME		**154,704,401**	**42,584,619**	**102,810,656**	**4,974,187**
Medicines control income	13	84,327,431	31,684,497	31,598,139	3,727,214
Laboratory services	14	9,509,643	6,430,999	4,925,837	768,390
Other income	15	60,867,327	4,469,123	66,286,680	478,583
EXPENDITURE		**60,154,250**	**45,705,532**	**30,051,976**	**5,094,488**
Employments costs	16	33,187,156	25,583,356	16,665,072	3,146,630
Administration costs	18	26,967,094	20,122,176	13,386,904	1,947,858
(Deficit)/surplus for the year		**94,550,151**	**(3,120,913)**	**72,758,680**	**(120,301)**
Monetary gain / (loss)		(41,037,078)	(6,971,073)	-	-
Surplus / (deficit) before taxation		53,513,073	(10,091,986)	72,758,680	(120,301)
Taxation	11	(41,855)	(17,151)	(41,855)	(2,761)
Surplus / (deficit) after taxation		53,471,218	(10,109,137)	72,716,825	(123,062)
Other comprehensive Income					
Revaluation gain		39,555,736	-	68,373,130	1,498,375
Total other comprehensive income		**39,555,736**	**-**	**68,373,130**	**1,498,375**
Total comprehensive income / (loss)		**93,026,954**	**(10,109,137)**	**141,089,955**	**1,375,313**
Surplus attributable to:					
Equity holders of the parent company		53,236,518	(10,216,457)	72,667,345	(126,326)
Non controlling interest		234,700	107,320	49,483	3,264
(Deficit)/surplus for the year		**53,471,218**	**(10,109,137)**	**72,716,828**	**(123,062)**
Other comprehensive income attributable to:					
Equity holders of the parent company		37,492,192	-	64,801,114	1,461,475
Non controlling interest		2,063,544	-	3,572,016	36,900
Surplus for the year		**39,555,736**	**-**	**68,373,130**	**1,498,375**

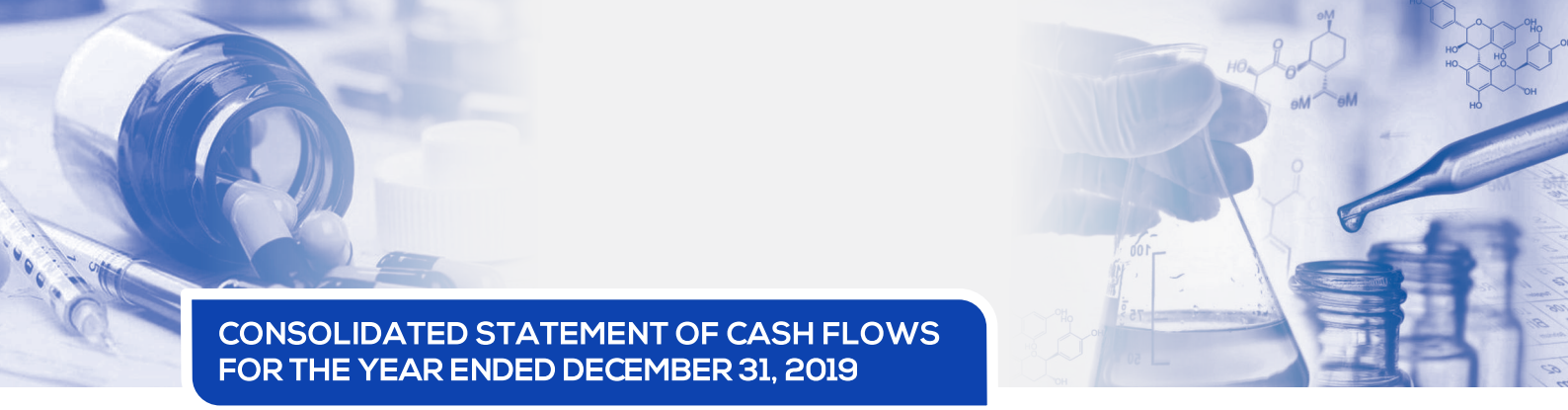


CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED DECEMBER 31, 2019

		AUTHORITY			
	Note	Inflation adjusted		Historical cost	
		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
INCOME		**153,938,518**	**42,336,289**	**102,585,910**	**4,944,157**
Medicines control income	13	84,327,431	31,684,497	31,598,139	3,727,214
Laboratory services	14	9,509,643	6,430,999	4,925,837	768,390
Other income	15	60,101,444	4,220,793	66,061,934	448,553
EXPENDITURE		**59,986,896**	**45,583,941**	**29,981,811**	**5,075,179**
Employments costs	16	33,187,156	25,583,356	16,665,072	3,146,630
Administration costs	18	26,799,740	20,000,585	13,316,739	1,928,549
(Deficit)/surplus for the year		**93,951,622**	**(3,247,652)**	**72,604,099**	**(131,022)**
Monetary gain / (loss)		**(38,471,310)**	(7,326,515)	**-**	-
Surplus / (deficit) before taxation		**55,480,312**	(10,574,167)	**72,604,099**	(131,022)
Taxation	11	**-**	-	**-**	-
Surplus / (deficit) after taxation		**55,480,312**	(10,574,167)	**72,604,099**	(131,022)
Other comprehensive Income					
Revaluation gain		34,522,701	-	59,649,854	1,408,375
Total other comprehensive income		**34,522,701**	-	**59,649,854**	**1,408,375**
Total comprehensive income / (loss)		**90,003,013**	**(10,574,167)**	**132,253,953**	**1,277,353**
Surplus attributable to:					
Equity holders of the parent company		55,480,312	**(10,574,167)**	72,604,099	**(131,022)**
Non controlling interest		-	-	-	-
(Deficit)/surplus for the year		**55,480,312**	(10,574,167)	**72,604,099**	(131,022)
Other comprehensive income attributable to:					
Equity holders of the parent company		34,522,701	-	59,649,854	**1,408,375**
Non controlling interest		-	-	-	-
Surplus for the year		**34,522,701**	-	**59,649,854**	1,408,375

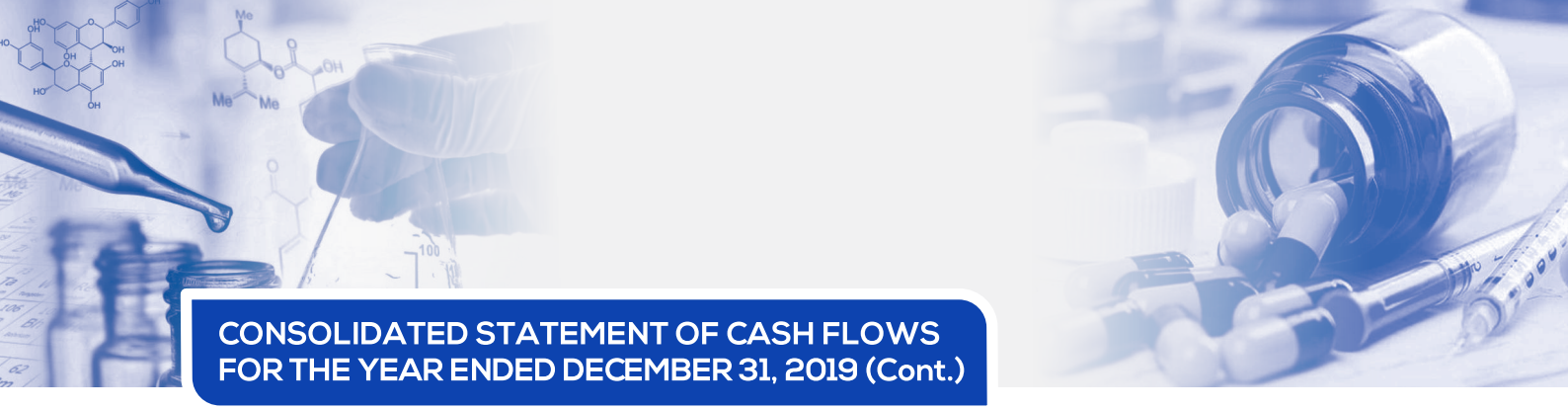
STATEMENT OF CHANGES IN RESERVES FOR THE YEAR ENDED DECEMBER 31, 2019

	Accumulated Fund	Capital Reserve	Revaluation Reserve	Total	Non Controlling Interest	Total Reserves
	ZWL$	ZWL$	ZWL$	ZWL$	ZWL$	ZWL$
Inflation adjusted						
Group						
Balance as at January 1, 2018	**(2,821,166)**	**52,682,803**	**-**	**49,861,637**	**1,826,119**	**51,687,756**
Surplus/(deficit) for the year	(10,216,457)	-		**(10,216,457)**	107,320	**(10,109,137)**
Balance as at December 31, 2018	**(13,037,623)**	**52,682,803**	**-**	**39,645,180**	**1,933,439**	**41,578,619**
Balance as at January 1, 2019	**(13,037,623)**	**52,682,803**	**-**	**39,645,180**	**1,933,439**	**41,578,619**
Surplus/(deficit) for the year	53,236,518	-	-	**53,236,518**	**234,700**	**53,471,218**
Other comprehensive income:	-	-	37,492,192	**37,492,192**	**2,063,544**	**39,555,736**
Balance as at December 31, 2019	**40,198,895**	**52,682,803**	**37,492,192**	**130,373,890**	**4,231,683**	**134,605,573**
Historical cost		-				
Balance as at January 1, 2018	**(1,142,060)**	**5,444,017**	**-**	**4,301,957**	**198,389**	**4,500,346**
				-		
Surplus/(deficit) for the year	(126,326)	-	-	**(126,326)**	3,264	**(123,062)**
Other comprehensive income:	-	-	-			
Revaluation	8,214	-	1,450,408	**1,458,622**	36,900	**1,495,522**
	-	-	-			
Balance as at December 31, 2018	**(1,260,172)**	**5,444,017**	**1,450,408**	**5,634,253**	**238,553**	**5,872,806**
Balance as at January 1, 2019	**(1,260,172)**	**5,444,017**	**1,450,408**	**5,634,253**	**238,553**	**5,872,806**
Capital reserve	-		-	**-**	**-**	**-**
Surplus/(deficit) for the year	72,667,345	-	-	**72,667,345**	**49,483**	**72,716,828**
Other comprehensive income:	-	-	-			
Revaluation	-	-	64,801,114	**64,801,114**	**3,572,016**	**68,373,130**
Balance as at December 31, 2019	**71,407,173**	**5,444,017**	**66,251,522**	**143,102,712**	**3,860,052**	**146,962,764**
Authority						
Inflation adjusted						
Balance as at January 1, 2018	(3,039,060)	52,682,803	-	**49,643,743**	-	49,643,743
Deficit for the year	(10,574,167)	-	-	**(10,574,167)**	-	(10,574,167)
Balance as at December 31, 2018	**(13,613,227)**	**52,682,803**	**-**	**39,069,576**	**-**	**39,069,576**
Balance as at January 1, 2019	**(13,613,227)**	**52,682,803**	**-**	**39,069,576**	**-**	**39,069,576**
Surplus/(deficit) for the year	55,480,312	-	-	**55,480,312**	-	55,480,312
	-	-	-			
Other comprehensive income: Revaluation	-	-	34,522,700	**34,522,700**		34,522,700
	-	-	-			
Balance as at December 31, 2019	**41,867,085**	**52,682,803**	**34,522,700**	**129,072,588**	**-**	**129,072,588**
Historical cost						
Balance as at January 1, 2018	(1,218,434)	5,444,017	-	**4,225,583**	-	4,225,583
Deficit for the year	(131,022)	-	-	**(131,022)**	-	(131,022)
Other comprehensive income:	-	-	-			
Revaluation	8,214	-	1,397,308	**1,405,522**	-	1,405,522
Balance as at December 31, 2018	**(1,341,242)**	**5,444,017**	**1,397,308**	**5,500,083**	**-**	**5,500,083**
Balance as at January 1, 2019	**(1,341,242)**	**5,444,017**	**1,397,308**	**5,500,083**	**-**	**5,500,083**
Surplus/(deficit) for the year	72,604,099	-	-	72,604,099	-	72,604,099
Other comprehensive income:	-	-	-			
Revaluation	-	-	59,649,854	59,649,854	-	59,649,854
Balance as at December 31, 2019	**71,262,857**	**5,444,017**	**61,047,162**	**137,754,036**	**-**	**137,754,036**



CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED DECEMBER 31, 2019

	Note	MCAZ GROUP			
		Inflation adjusted		Historical cost	
		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
Net cash flow from operating activities		**42,161,641**	**1,864,892**	**46,379,133**	**569,555**
(Deficit) / surplus for the year		94,550,151	(3,120,913)	72,758,680	(120,301)
Adjusted for non cash items:		**(52,704,237)**	**8,913,169**	**(28,771,684)**	**181,509**
Depreciation	4	2,211,046	2,996,588	2,645,105	333,148
(Decrease)/increase in provision for leave pay		(962,926)	(598,972)	(17,688)	(9,772)
Fair value adjustment on investment property		(15,679,693)	(4,257,310)	(24,226,900)	(40,000)
Deferred income amortisation	15	(1,913,024)	(522,254)	(79,083)	(82,674)
Profit on disposal of property, plant and equipment		-	(128,386)	-	(15,159)
Loss on disposal of property, plant and equipment		420,676	-	46,379	-
Interest earned		(12,693)	(31,170)	(5,788)	(4,034)
Exchange gains-unrealised		(7,133,709)	-	(7,133,709)	-
Effect of monetary movement		(29,633,914)	11,454,673	-	-
Working capital changes:		**315,727**	**(3,927,364)**	**2,392,137**	**508,347**
Decrease/(increase) in inventory		(128,707)	55,789	(266,813)	2,609
Decrease/(increase) in trade and other receivables		982,079	(982,079)	(2,321,048)	212,942
Increase/(decrease) in trade and other payables		(537,645)	(3,001,074)	4,979,998	292,796
Taxation		(19,871)	(70,113)	(7,040)	(8,262)
Net cash flow from investing activities:		**(2,143,255)**	**(1,265,913)**	**(731,592)**	**(164,221)**
Purchase of property, plant and equipment		(2,214,274)	(1,523,070)	(747,237)	(191,726)
Proceeds from disposal of property, plant and equipment		58,326	225,987	9,857	23,471
Interest received		12,693	31,170	5,788	4,034
Net cash flow from financing activities:		**(15,933)**	**-**	**(2,565)**	**-**
Staff vehicle contribution scheme		(15,933)	-	(2,565)	-
Net increase/(decrease) in cash and cash equivalents		**39,982,582**	**528,866**	**45,637,936**	**397,072**
Exchange gains-unrealised		7,133,709	-	7,133,709	-
Cash and cash equivalents at beginning of the year		6,740,478	6,211,612	1,085,124	688,052
Cash and cash equivalents at year end	9	**53,856,769**	**6,740,478**	**53,856,769**	**1,085,124**



CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED DECEMBER 31, 2019 (Cont.)

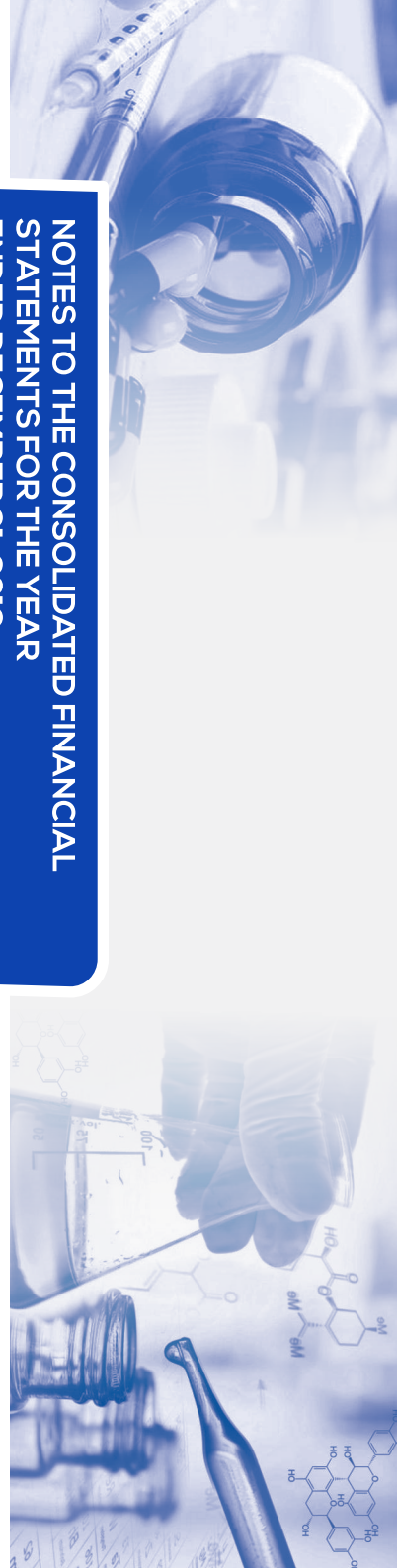
	Note	AUTHORITY			
		Inflation adjusted		Historical cost	
		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
Net cash flow from operating activities		**42,209,595**	**1,818,463**	**46,376,519**	**557,120**
(Deficit) / surplus for the year		93,951,622	(3,247,652)	72,604,099	(131,022)
Adjusted for non cash items:		**(52,103,098)**	**8,931,137**	**(28,783,166)**	**176,573**
Depreciation	4	2,176,455	2,963,483	2,633,556	328,182
(Decrease)/increase in provision for leave pay		(962,926)	(598,972)	(17,688)	(9,772)
Fair value adjustment on investment property		(15,679,693)	(4,257,310)	(24,226,900)	(40,000)
Deferred income amortisation	15	(1,913,024)	(522,254)	(79,083)	(82,674)
Profit on disposal of property, plant and equipment		-	(128,386)	-	(15,159)
Loss on disposal of property, plant and equipment		420,676	-	46,379	-
Interest earned		(12,693)	(30,927)	(5,721)	(4,004)
Exchange gains-unrealised		(7,133,709)		(7,133,709)	-
Effect of monetary movement		(28,998,184)	11,505,503	-	-
Working capital changes:		**361,071**	**(3,865,022)**	**2,555,586**	**511,569**
Decrease/(increase) in inventory		(128,707)	55,789	(266,813)	2,609
Decrease/(increase) in trade and other receivables		908,794	(908,794)	(2,332,846)	213,409
Increase/(decrease) in trade and other payables		(419,016)	(3,012,017)	5,155,245	295,551
Taxation		(19,874)		-	
Net cash flow from investing activities:		**(2,143,255)**	**(1,251,311)**	**(731,659)**	**(159,606)**
Purchase of property, plant and equipment		(2,214,274)	(1,508,225)	(747,237)	(187,081)
Proceeds from disposal of property, plant and equipment		58,326	225,987	9,857	23,471
Interest received		12,693	30,927	5,721	4,004
Net cash flow from financing activities:		**(15,933)**	**-**	**(2,565)**	**-**
Staff vehicle contribution scheme		(15,933)	-	(2,565)	-
Net increase/(decrease) in cash and cash equivalents		**40,050,407**	**567,152**	**45,642,295**	**397,514**
Exchange gains-unrealised		7,133,709	-	7,133,709	-
Cash and cash equivalents at beginning of the year		6,664,834	6,097,682	1,072,946	675,432
Cash and cash equivalents at year end	9	**53,848,950**	**6,664,834**	**53,848,950**	**1,072,946**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019

MCAZ GROUP

Property, plant and equipment

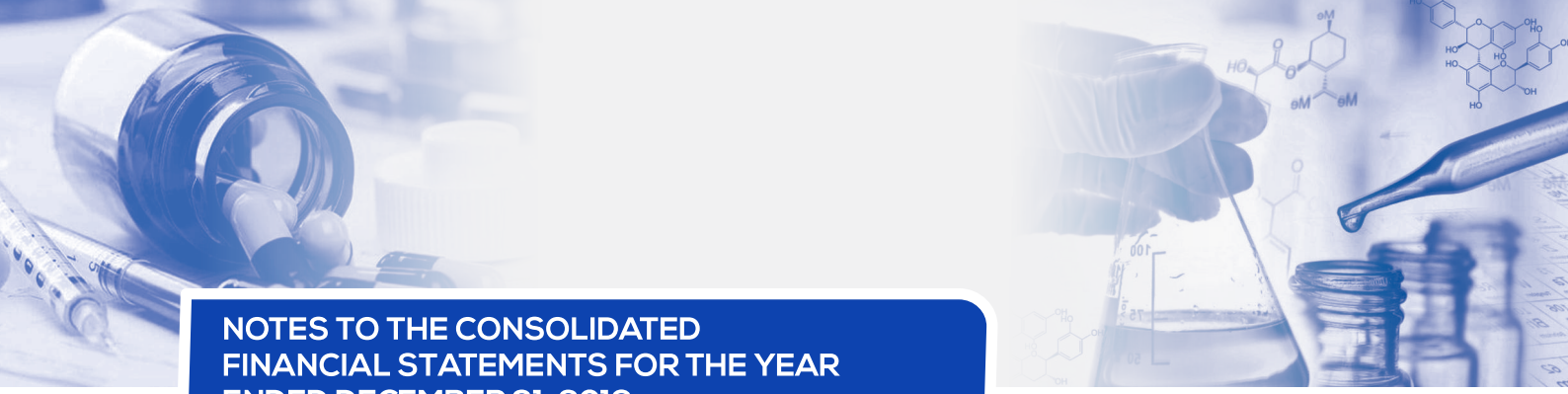
Note 4.0	Freehold Land	Buildings	Plant & Machinery	Motor Vehicles	Computer & Equipment	Office Equipment	Furniture & Fittings	Work in Progress	Total 2019	Total 2018
		ZWL$	ZWL$	ZWL$	ZWL$	ZWL$	ZWL$	ZWL$	ZWL$	ZWL$
Inflation adjusted										
Opening carrying amount	**10,899,037**	**14,968,314**	**3,074,882**	**754,584**	**416,198**	**175,281**	**1,377,739**	**817,641**	**32,483,676**	**34,054,795**
Gross carrying amount	10,899,037	17,798,144	9,194,659	2,929,899	2,643,179	818,563	1,669,932	817,641	46,771,054	46,147,691
Accumulated depreciation	-	(2,829,830)	(6,119,777)	(2,175,315)	(2,226,981)	(643,282)	(292,193)	-	(14,287,378)	(12,092,896)
Additions at cost	**-**	**-**	**2,389,739**	**-**	**704,337**	**23,504**	**65,347**	**1,512,345**	**4,695,272**	**1,523,070**
Purchased assets at cost	-	-	20,371	-	592,707	23,504	65,347	1,512,345	2,214,274	1,523,070
Donated assets at cost	-	-	2,369,368	-	111,630	-	-	-	2,480,998	-
Revaluation	16,560,848	13,443,861	7,063,128	1,834,315	388,680	33,447	231,457	-	39,555,736	-
Disposals carrying amount			**(308,860)**	**(43,457)**	**(622)**	**(26,998)**	**(99,065)**		**(479,002)**	**(97,601)**
Disposals at cost	-	-	(6,514,606)	(530,334)	(498,279)	(232,939)	(314,888)	-	(8,091,046)	(899,706)
Accumulated depreciation on disposals	-	-	6,205,746	486,877	497,657	205,941	215,823	-	7,612,044	802,105
Depreciation for the year	-	(857,182)	(548,147)	(245,441)	(350,707)	(93,567)	(116,002)	-	(2,211,046)	(2,996,588)
Closing carrying amount	**27,459,885**	**27,554,993**	**11,670,742**	**2,300,001**	**1,157,886**	**111,667**	**1,459,476**	**2,329,986**	**74,044,636**	**32,483,676**
Gross carrying amount	27,459,885	31,242,005	12,132,920	4,233,880	3,237,917	642,575	1,651,848	2,329,986	82,931,016	46,771,055
Accumulated depreciation	-	(3,687,012)	(462,178)	(1,933,879)	(2,080,031)	(530,908)	(192,372)	-	(8,886,380)	(14,287,379)
Historical cost										
Opening carrying amount	**1,740,001**	**1,558,465**	**409,837**	**131,147**	**54,258**	**25,030**	**91,387**	**111,778**	**4,121,903**	**2 776 115**
Gross carrying amount	1,740,001	1,850,000	1,895,839	568,014	369,109	116,409	217,044	111,778	6,868,194	5,280,399
Accumulated depreciation	-	(291,535)	(1,486,002)	(436,867)	(314,851)	(91,379)	(125,657)	-	(2,746,291)	(2,504,284)
Additions at cost	-		2,389,740	-	308,848	23,504	14,690	491,453	3,228,235	**191,726**
Purchased assets at cost	-		20,372	-	197,218	23,504	14,690	491,453	747,237	191,726
Donated assets at cost	-		2,369,368	-	111,630	-	-	-	2,480,998	-
Revaluation	**25,719,885**	**26,630,192**	**11,188,117**	**2,559,427**	**634,429**	**183,169**	**1,457,911**	**-**	68,373,130	**1,498,375**
Revaluation cost	25,719,885	30,885,119	26,059,087	13,475,819	4,349,490	1,382,699	3,682,198	0	105,554,297	1,498,375
Revaluation accumulated depreciation	-	(4,254,927)	(14,870,970)	(10,916,392)	(3,715,061)	(1,199,530)	(2,224,287)	-	(37,181,167)	-
Disposals carrying amount		**-**	**(34,734)**	**(6,933)**	**(69)**	**(3,081)**	**(11,419)**	-	**(56,236)**	**(11,165)**
Disposals at cost	-	-	(674,208)	(83,817)	(52,493)	(24,596)	(34,776)	-	(869,890)	(102,306)
Accumulated depreciation on disposals	-	-	639,474	76,884	52,424	21,515	23,357	-	813,654	91,141
Depreciation for the year	-	(633,663)	(1,295,219)	(383,600)	(158,300)	(28,637)	(145,686)	-	(2,645,105)	(333,148)
Closing carrying amount	**27,459,886**	**27,554,994**	**12,657,741**	**2,300,041**	**839,166**	**199,985**	**1,406,883**	**603,231**	73,021,927	**4,121,903**
Gross carrying amount	27,459,886	32,735,119	29,670,458	13,960,016	4,974,954	1,498,016	3,879,156	603,231	114,780,836	6,868,194
Accumulated depreciation	-	(5,180,125)	(17,012,717)	(11,659,975)	(4,135,788)	(1,298,031)	(2,472,273)	-	(41,758,909)	(2,746,291)



AUTHORITY

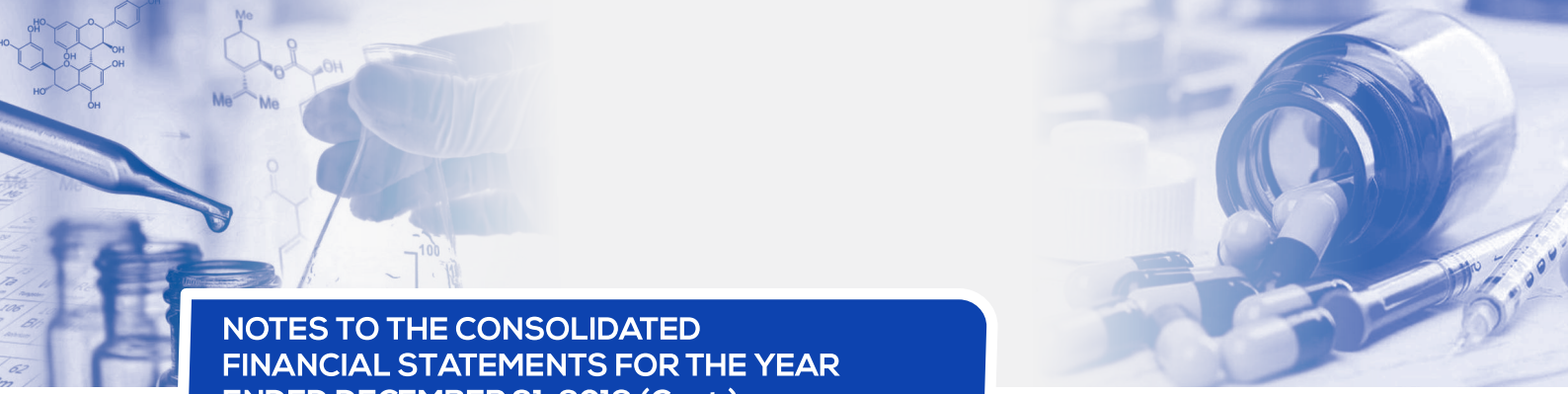
Property, plant and equipment

Note 4.1	Freehold Land ZWL$	Buildings ZWL$	Plant & Machinery ZWL$	Motor Vehicles ZWL$	Computer & Equipment ZWL$	Office Equipment ZWL$	Furniture & Fittings ZWL$	Work in Progress ZWL$	Total 2019 ZWL$	Total 2018 ZWL$
Inflation adjusted										
Opening carrying amount	**7,694,160**	**13,898,896**	**3,056,625**	**754,584**	**416,198**	**175,281**	**1,377,739**	**817,641**	**28,191,124**	**29,743,983**
Gross carrying amount	7,694,160	16,489,110	9,176,023	2,929,899	2,643,179	818,563	1,669,932	817,641	42,238,507	41,629,988
Accumulated depreciation	-	(2,590,214)	(6,119,398)	(2,175,315)	(2,226,981)	(643,282)	(292,193)	-	(14,047,383)	(11,886,005)
Additions at cost	**-**	**-**	**2,389,739**	**-**	**704,337**	**23,504**	**65,347**	**1,512,345**	**4,695,272**	**1,508,225**
Purchased assets at cost	-	-	20,371	-	592,707	23,504	65,347	1,512,345	2,214,274	1,508,225
Donated assets at cost	-	-	2,369,368	-	111,630	-	-	-	2,480,998	-
Revaluation	13,141,275	11,830,399	7,063,128	1,834,315	388,680	33,447	231,457	-	**34,522,701**	-
Disposals carrying amount	**-**	**-**	**(308,860)**	**(43,457)**	**(622)**	**(26,998)**	**(99,065)**	-	**(479,002)**	**(97,601)**
Disposals at cost			(6,514,606)	(530,334)	(498,279)	(232,939)	(314,888)		(8,091,046)	(899,706)
Accumulated depreciation on disposals	-	-	6,205,746	486,877	497,657	205,941	215,823	-	7,612,044	802,105
Depreciation for the year	-	(824,456)	(546,282)	(245,441)	(350,707)	(93,567)	(116,002)	-	(2,176,455)	(2,963,483)
Closing carrying amount	**20,835,435**	**24,904,839**	**11,654,350**	**2,300,001**	**1,157,886**	**111,667**	**1,459,476**	**2,329,986**	**64,753,640**	**28,191,124**
Gross carrying amount	20,835,435	28,319,509	12,114,284	4,233,880	3,237,917	642,575	1,651,848	2,329,986	73,365,434	42,238,507
Accumulated depreciation	-	(3,414,670)	(459,934)	(1,933,879)	(2,080,031)	(530,908)	(192,372)	-	(8,611,794)	(14,047,383)
Historical cost										
Opening carrying amount	**1,320,001**	**1,416,095**	**405,025**	**131,147**	**54,258**	**25,030**	**91,387**	**111,778**	**3,554,721**	**2,298,612**
Gross carrying amount	1,320,001	1,680,000	1,890,774	568,014	369,109	116,409	217,044	111,778	6,273,129	4,779,979
Accumulated depreciation	-	(263,905)	(1,485,749)	(436,867)	(314,851)	(91,379)	(125,657)	-	(2,718,408)	(2,481,367)
Additions at cost	**-**	**-**	**2,389,740**	**-**	**308,848**	**23,504**	**14,690**	**491,453**	**3,228,235**	**187,081**
Purchased assets at cost	-	-	20,372	-	197,218	23,504	14,690	491,453	747,237	187,081
Donated assets at cost			2,369,368		111,630				2,480,998	
Revaluation	**19,515,435**	**24,111,366**	**11,188,117**	**2,559,427**	**634,429**	**183,169**	**1,457,911**	-	**59,649,854**	**1,408,375**
Revaluation cost	19,515,435	28,235,806	26,059,087	13,475,819	4,349,490	1,382,699	3,682,198	-	96,700,534	1,408,375
Revaluation accumulated depreciation	-	(4,124,440)	(14,870,970)	(10,916,392)	(3,715,061)	(1,199,530)	(2,224,287)	-	(37,050,680)	-
Disposals carrying amount	-	-	**(34,734)**	**(6,933)**	**(69)**	**(3,081)**	**(11,419)**	-	**(56,236)**	**(11,165)**
Disposals at cost	-	-	(674,208)	(83,817)	(52,493)	(24,596)	(34,776)	-	(869,890)	(102,306)
Accumulated depreciation on disposals	-	-	639,474	76,884	52,424	21,515	23,357	-	813,654	91,141
Depreciation for the year	-	(622,621)	(1,294,712)	(383,600)	(158,300)	(28,637)	(145,686)	-	(2,633,556)	(328,182)
Closing carrying amount	**20,835,436**	**24,904,840**	**12,653,436**	**2,300,041**	**839,166**	**199,985**	**1,406,883**	**603,231**	**63,743,018**	**3,554,721**
Gross carrying amount	20,835,436	29,915,806	29,665,393	13,960,016	4,974,954	1,498,016	3,879,156	603,231	105,332,008	6,273,129
Accumulated depreciation	-	(5,010,966)	(17,011,957)	(11,659,975)	(4,135,788)	(1,298,031)	(2,472,273)	-	(41,588,990)	(2,718,408)



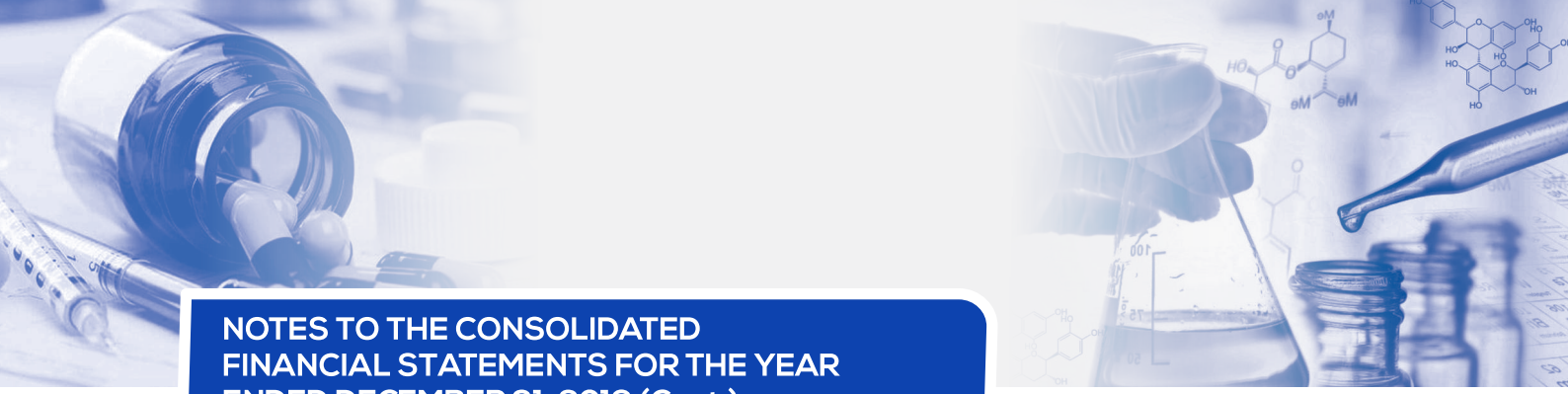
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019

		Inflation adjusted		Historical cost	
		MCAZ GROUP			
Note		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
5	**Investment property**				
	Opening fair value	10,187,207	14,444,517	1,640,000	1,600,000
	Fair value adjustment	15,679,693	(4,257,310)	24,226,900	40,000
	Closing value	**25,866,900**	**10,187,207**	**25,866,900**	**1,640,000**
6	**Investment in subsidiary**				
	Percentage Discount Pvt Ltd	-	-	-	-
		-	-	-	-
7	**Inventories**				
	Fuel	165,670	24,785	165,670	3,990
	Provisions	56,731	36,038	48,235	4,947
	Stationery consumables	100,046	132,917	80,548	18,703
		322,447	**193,740**	**294,453**	**27,640**
8	**Trade and other receivables**				
	Trade receivables	1,780,465	4,917,874	1,780,465	791,710
	Allowance for credit losses	(56,099)	(1,527,174)	(56,099)	(245,854)
	Other receivables	402,585	373	402,585	60
	Rentals - Mishonga Gardens	28,708	178,326	28,708	28,708
	Staff receivables	95,090	18,262	95,090	2,940
	Related party receivables	-	-	-	-
	Sundry receivables	657,748	349,255	657,748	56,225
	Short term investments	46,340	-	46,340	-
		2,954,837	**3,936,916**	**2,954,837**	**633,789**
9	**Cash and cash equivalents**				
	Bank	53,856,435	6,738,515	53,856,435	1,084,808
	Funds on placement	334	1,963	334	316
		53,856,769	**6,740,478**	**53,856,769**	**1,085,124**
10	**Deferred income**				
	Opening carrying amount	4,178,033	4,700,287	382,312	464,986
	Additions of donated equipment	13,907,701	-	2,480,997	-
	Amortisation charge for the year	(1,913,024)	(522,254)	(79,083)	(82,674)
		16,172,710	**4,178,033**	**2,784,226**	**382,312**



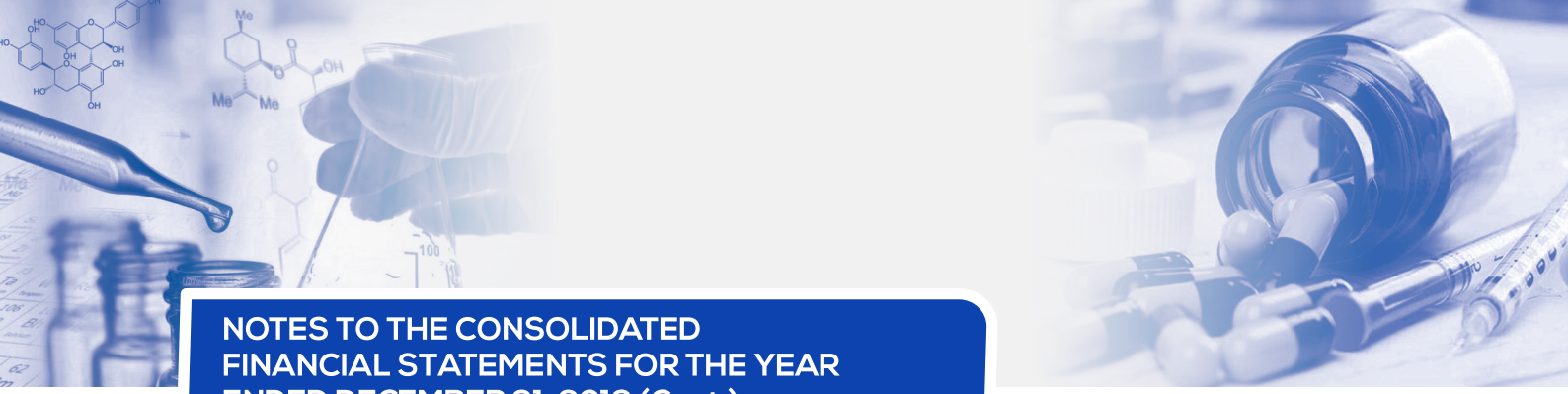
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019 (Cont.)

		Inflation adjusted		Historical cost	
		AUTHORITY			
Note		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
5	**Investment property**				
	Opening fair value	10,187,207	14,444,517	1,640,000	1,600,000
	Fair value adjustment	15,679,693	(4,257,310)	24,226,900	40,000
	Closing value	**25,866,900**	**10,187,207**	**25,866,900**	**1,640,000**
6	**Investment in subsidiary**				
	Percentage Discount Pvt Ltd	3,887,015	1,933,439	218,595	218,595
		3,887,015	**1,933,439**	**218,595**	**218,595**
7	**Inventories**				
	Fuel	165,670	24,785	165,670	3,990
	Provisions	56,731	36,038	48,235	4,947
	Stationery consumables	100,046	132,917	80,548	18,703
		322,447	**193,740**	**294,453**	**27,640**
8	**Trade and other receivables**				
	Trade receivables	1,780,465	4,844,589	1,780,465	779,912
	Allowance for credit losses	(56,099)	(1,527,174)	(56,099)	(245,854)
	Other receivables	402,585	373	402,585	60
	Rentals - Mishonga Gardens	28,708	178,326	28,708	28,708
	Staff receivables	95,090	18,262	95,090	2,940
	Related party receivables	-	-	-	-
	Sundry receivables	657,748	349,255	657,748	56,225
	Short term investments	46,340	-	46,340	-
		2,954,837	**3,863,631**	**2,954,837**	**621,991**
9	**Cash and cash equivalents**				
	Bank	53,848,616	6,662,871	53,848,616	1,072,630
	Funds on placement	334	1,963	334	316
		53,848,950	**6,664,834**	**53,848,950**	**1,072,946**
10	**Deferred income**				
	Opening carrying amount	4,178,033	4,700,287	382,312	464,986
	Additions of donated equipment	13,907,701	-	2,480,997	-
	Amortisation charge for the year	(1,913,024)	(522,254)	(79,083)	(82,674)
		16,172,710	**4,178,033**	**2,784,226**	**382,312**



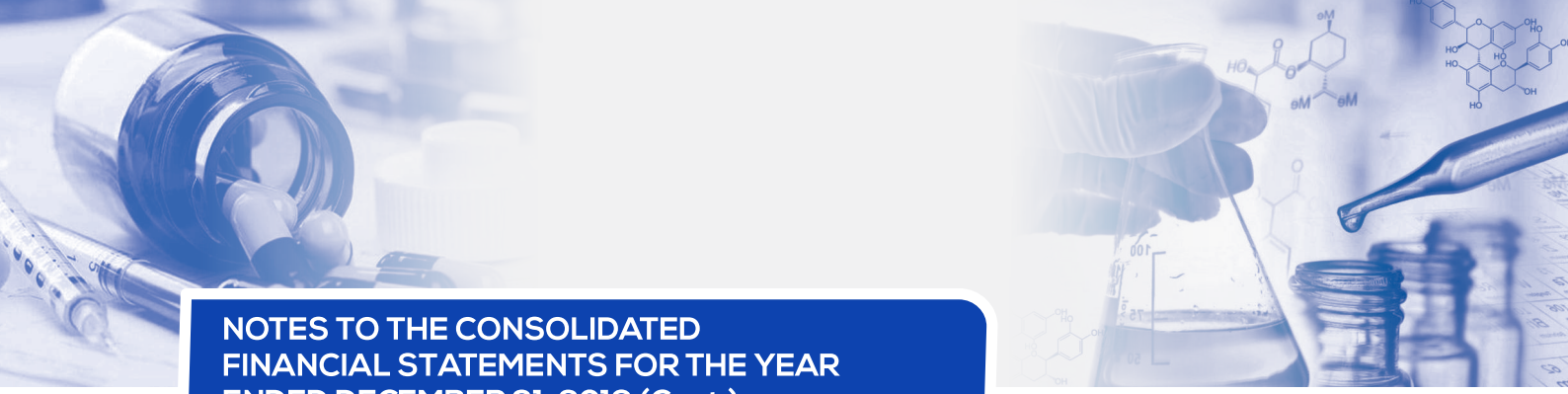
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019 (Cont.)

		Inflation adjusted		Historical cost	
		MCAZ GROUP			
Note		2019	2018	2019	2018
11	**Income tax expense**	ZWL$	ZWL$	ZWL$	ZWL$
	Major components of tax expense				
	Current tax				
	Current tax	43,409	2,761	43,409	53,779
	Deferred tax	(1,554)	14,390	(1,554)	(51,018)
		41,855	**17,151**	**41,855**	**2,761**
11.1	**Tax reconciliation**				
	Profit before tax	162,545	99,305	162,545	10,721
	Notional tax thereon at a rate of 25.75%	41,855	17,151	41,855	2,761
		41,855	**17,151**	**41,855**	**2,761**
	Current tax				
11.2	Balance as at 1 January	17,146	70,107	2,761	8,262
	Current year charge	41,855	17,151	43,409	2,761
	Payments	(19,871)	(70,113)	(7,040)	(8,262)
	Balance as at 31 December	**39,130**	**17,145**	**39,130**	**2,761**
	Deferred tax				
	Balance at 1 January	23,138	8,748	3,726	54,744
	Movements	(1,554)	14,390	(1,553)	(51,018)
	Net deffered tax liabilitiy	**21,584**	**23,138**	**2,173**	**3,726**



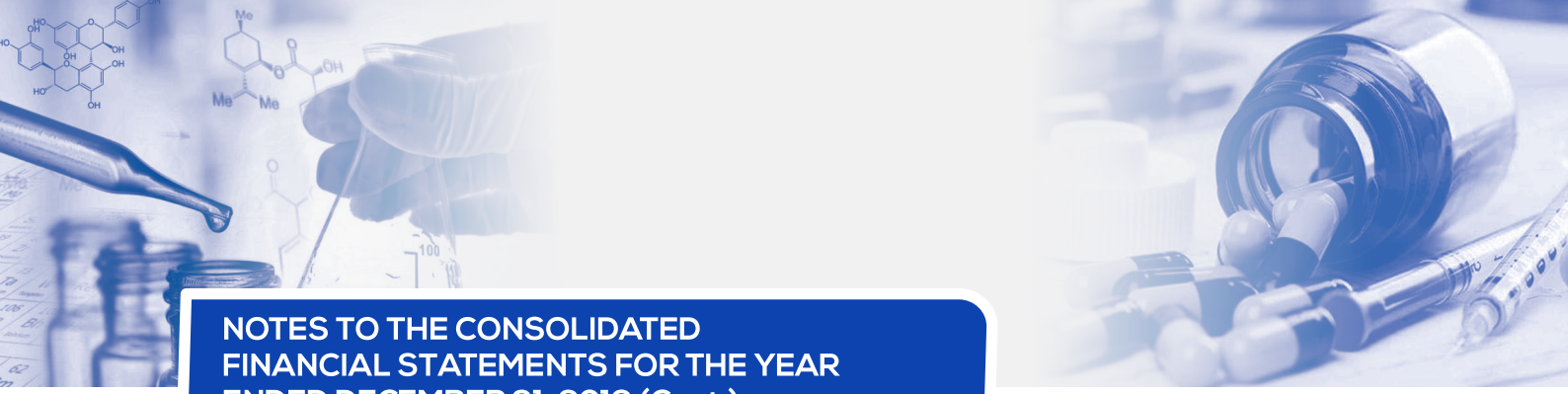
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019 (Cont.)

		Inflation adjusted		Historical cost	
		MCAZ GROUP			
Note		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
12	**Trade and other payables**				
	Audit fees	-	95,194	-	15,325
	Trade payables	979,834	430,282	979,834	69,270
	Sundry payables	1,100,911	5,969,542	1,100,911	961,014
	Related party payables	-	-	-	-
	Other payables	3,760,013	-	3,760,013	-
	Tax payable	39,353	17,151	39,353	2,761
	Unallocated income	201,932	107,519	201,932	17,309
		6,082,043	**6,619,688**	**6,082,043**	**1,065,679**
13	**Medicines control income**				
	Amendment fees	1,813,420	1,184,519	874,014	143,050
	Clinical trials	750,673	204,354	377,755	24,100
	Dangerous drug license	37,083,335	-	13,381,366	-
	Drug registration forensic examination	26,005	189,615	7,450	22,730
	Import and export licenses	3,417,511	3,324,770	1,489,277	391,751
	Inspection	10,887,372	3,490,917	4,492,015	416,600
	Persons and premises licenses	745,816	1,364,685	208,985	162,517
	Registration fees	9,856,435	6,875,913	4,371,998	826,492
	Renewal of licenses	2,809,482	3,644,690	557,730	417,810
	Retention fees	15,609,410	7,711,589	5,424,979	886,456
	Sales representatives and wholesale dealers	223,114	1,584,814	70,900	183,540
	Unregistered medicines	768,710	1,517,184	260,870	181,738
	Veterinary permits	336,148	591,447	80,800	70,430
		84,327,431	**31,684,497**	**31,598,139**	**3,727,214**
14	**Laboratory services income**				
	Condom testing	910,286	705,546	508,595	84,890
	Complementary medicines	-	379,283	-	47,400
	Glove testing	203,319	105,005	94,376	12,650
	Medical devices-registration	-	16,553	-	2,000
	Samples-external clients	8,396,038	5,224,612	4,322,866	621,450
		9,509,643	**6,430,999**	**4,925,837**	**768,390**



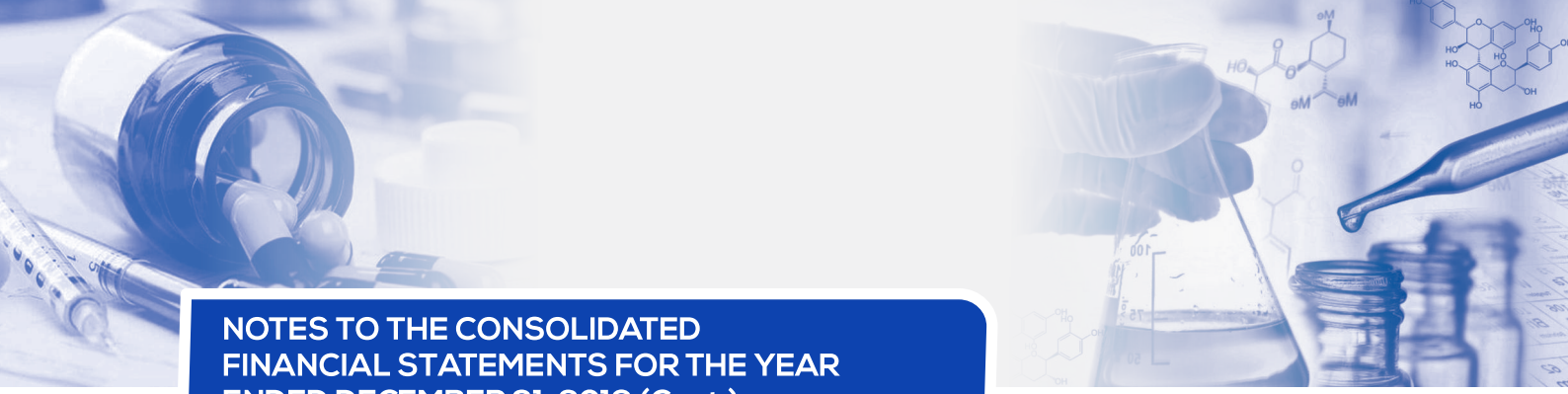
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019 (Cont.)

		Inflation adjusted		Historical cost	
		AUTHORITY			
Note		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
12	**Trade and other payables**				
	Audit fees	-	95,194	-	15,325
	Trade payables	979,834	430,282	979,834	69,270
	Sundry payables	1,100,911	5,962,753	1,100,911	959,921
	Related party payables	182,121	48,079	182,121	7,740
	Other payables	3,760,013	-	3,760,013	-
	Tax payable	-	-	-	-
	Unallocated income	201,932	107,519	201,932	17,309
		6,224,811	**6,643,827**	**6,224,811**	**1,069,565**
13	**Medicines control income**				
	Amendment fees	1,813,420	1,184,519	874,014	143,050
	Clinical trials	750,673	204,354	377,755	24,100
	Dangerous drug license	37,083,335	-	13,381,366	-
	Drug registration forensic examination	26,005	189,615	7,450	22,730
	Import and export licenses	3,417,511	3,324,770	1,489,277	391,751
	Inspection	10,887,372	3,490,917	4,492,015	416,600
	Persons and premises licenses	745,816	1,364,685	208,985	162,517
	Registration fees	9,856,435	6,875,913	4,371,998	826,492
	Renewal of licenses	2,809,482	3,644,690	557,730	417,810
	Retention fees	15,609,410	7,711,589	5,424,979	886,456
	Sales representatives and wholesale dealers	223,114	1,584,814	70,900	183,540
	Unregistered medicines	768,710	1,517,184	260,870	181,738
	Veterinary permits	336,148	591,447	80,800	70,430
		84,327,431	**31,684,497**	**31,598,139**	**3,727,214**
14	**Laboratory services income**				
	Condom testing	910,286	705,546	508,595	84,890
	Complementary medicines	-	379,283	-	47,400
	Glove testing	203,319	105,005	94,376	12,650
	Medical devices-registration	-	16,553	-	2,000
	Samples-external clients	8,396,038	5,224,612	4,322,866	621,450
		9,509,643	**6,430,999**	**4,925,837**	**768,390**



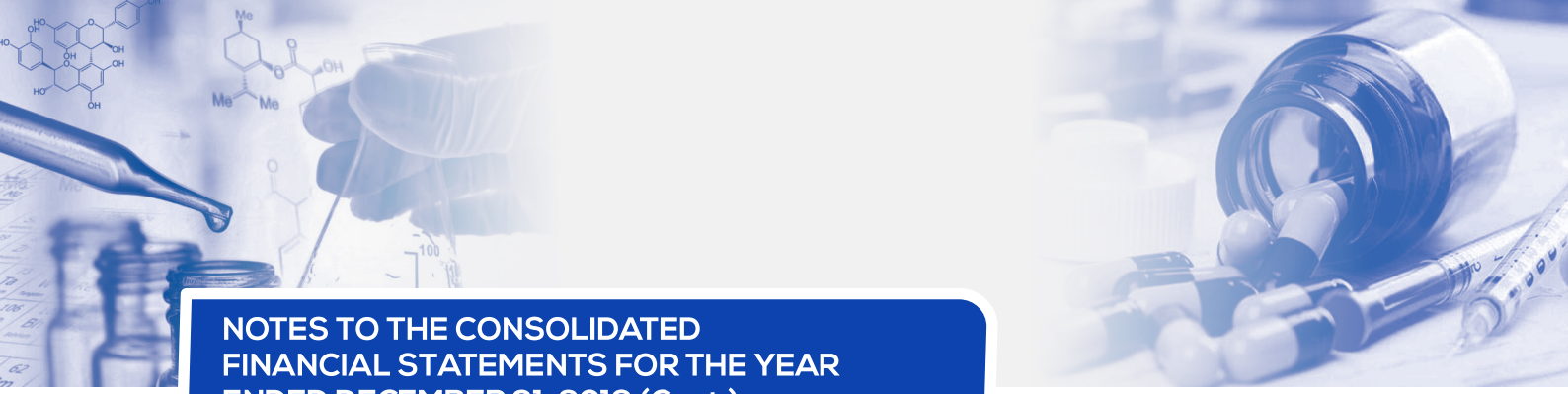
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019 (Cont.)

		Inflation adjusted		Historical cost	
		MCAZ GROUP			
Note		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
15	**Other income**				
	Amortisation for the year	1,913,024	522,254	79,083	82,674
	Decrease in provision for leave pay	962,926	598,972	17,688	9,772
	Dividend received	-	-	-	-
	Donations	459,643	940,998	253,552	111,876
	Interest earned	12,693	31,170	5,788	4,034
	Rentals	1,484,759	1,489,154	584,296	178,571
	Fair value adjustment	15,679,693	-	24,226,900	40,000
	Sundry income	1,255,366	304,316	680,519	36,497
	Profit on disposal of property, plant and equipment	-	128,386	-	15,159
	Exchange gain/loss - realised	30,494,439	-	33,115,390	-
	Exchange gain/loss - unrealised	7,133,709	-	7,133,709	-
	Decrease in provision for credit losses	1,471,075	453,873	189,755	-
		60,867,327	**4,469,123**	**66,286,680**	**478,583**
16	**Employment costs**				
	Salaries and wages	28,244,902	22,236,104	14,212,060	2,736,266
	Pension and medical aid	1,783,460	2,751,596	698,683	332,509
	Staff training expenses	2,310,028	114,351	1,160,598	14,416
	Staff welfare	848,766	481,305	593,731	63,439
		33,187,156	**25,583,356**	**16,665,072**	**3,146,630**
17	**Related party transactions**				
	The remuneration of the board members and other key management personnel during the financial year was as follows:				
17.1	Board members benefits	22,348	340,475	8,451	43,684
	Board members fees	628,242	1,349,750	299,552	164,050
		650,590	**1,690,225**	**308,003**	**207,734**
17.2	**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	50,716	111,393	19,333	13,269
	Director General salary	914,188	701,391	416,618	83,529
		964,904	**812,784**	**435,951**	**96,798**



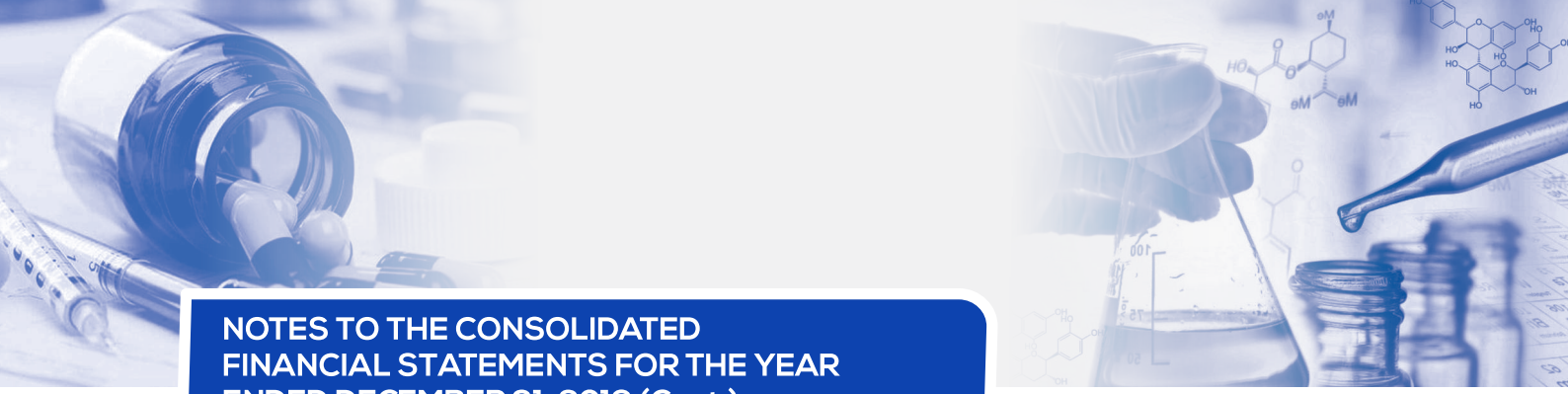
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019 (Cont.)

		Inflation adjusted		Historical cost	
		AUTHORITY			
Note		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
15	**Other income**				
	Amortisation for the year	1,913,024	522,254	79,083	82,674
	Decrease in provision for leave pay	962,926	598,972	17,688	9,772
	Dividend received	4,696	-	4,696	-
	Donations	459,643	940,998	253,552	111,876
	Interest earned	12,693	30,927	5,721	4,004
	Rentals	761,454	1,241,067	363,831	148,571
	Fair value adjustment	15,679,693	-	24,226,900	40,000
	Sundry income	1,208,092	304,316	671,609	36,497
	Profit on disposal of property, plant and equipment	-	128,386	-	15,159
	Exchange gain/loss - realised	30,494,439	-	33,115,390	-
	Exchange gain/loss - unrealised	7,133,709	-	7,133,709	-
	Decrease in provision for credit losses	1,471,075	453,873	189,755	-
		60,101,444	**4,220,793**	**66,061,934**	**448,553**
16	**Employment costs**				
	Salaries and wages	28,244,902	22,236,104	14,212,060	2,736,266
	Pension and medical aid	1,783,460	2,751,596	698,683	332,509
	Staff training expenses	2,310,028	114,351	1,160,598	14,416
	Staff welfare	848,766	481,305	593,731	63,439
		33,187,156	**25,583,356**	**16,665,072**	**3,146,630**
17	**Related party transactions**				
	The remuneration of the board members and other key management personnel during the financial year was as follows:				
17.1	Board members benefits	22,348	340,475	8,451	43,684
	Board members fees	611,367	1,319,469	292,676	160,375
		633,715	**1,659,944**	**301,127**	**204,059**
17.2	**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	50,716	111,393	19,333	13,269
	Director General salary	914,188	701,391	416,618	83,529
		964,904	**812,784**	**435,951**	**96,798**

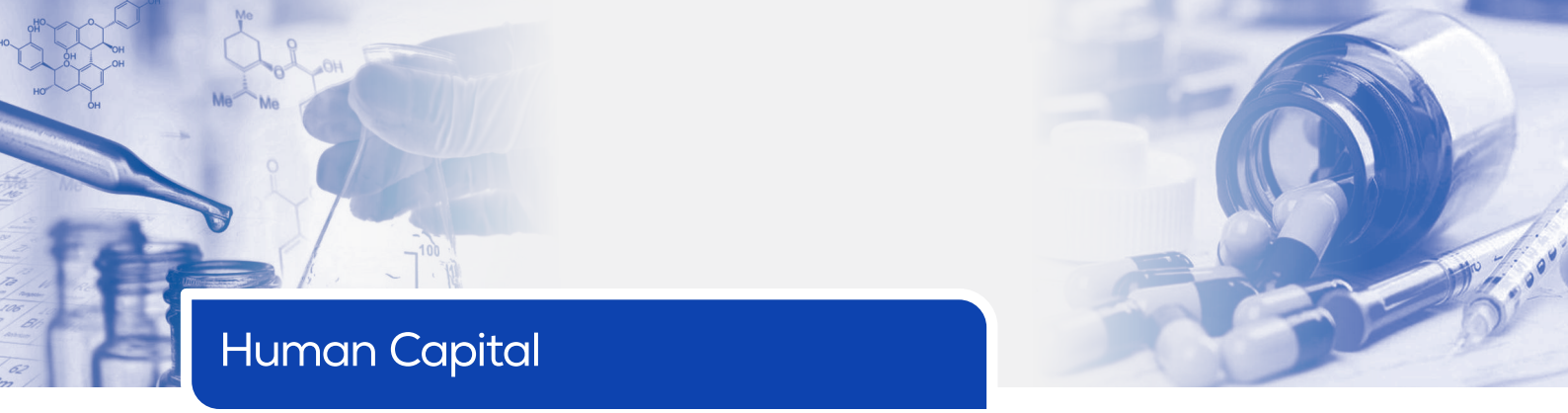


NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019 (Cont.)

		Inflation adjusted		Historical cost	
		MCAZ GROUP			
Note		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
18	**Administration expenses**				
	Audit fees	72,861	141,363	22,800	16,500
	Board fees	2,641,899	1,690,224	1,313,815	207,734
	Bank charges	865,019	286,408	372,754	40,390
	Communications	159,308	434,396	64,837	53,735
	Consumables	297,060	354,616	108,270	42,487
	Credit losses	203,701	-	22,379	-
	Credit losses movement	-	-	-	26,416
	Directors expenses	-	172,721	-	21,240
	Depreciation	2,211,046	2,996,588	2,645,102	333,148
	Fair value adjustment	-	4,257,310	-	-
	General administration	1,048,345	895,399	509,356	112,765
	Inspections	5,533,063	1,801,588	2,161,932	215,296
	IT expenses	1,279,400	75,371	742,079	8,635
	Legal and professional fees	506,486	436,201	289,364	57,196
	Printing and stationery	740,380	706,390	434,777	92,762
	Loss on disposal of property, plant and equipment	420,676	-	46,379	-
	Public relations	447,819	643,127	213,930	77,753
	Quality assurance costs	143,830	129,085	42,695	17,788
	Rates, electricity and water	108,204	194,570	52,646	24,306
	Repairs and maintenance	1,819,128	1,246,921	892,075	147,595
	Security and insurance costs	530,055	332,755	278,100	41,310
	Strategic planning	6,227,209	962,229	2,345,046	124,765
	Subscriptions	192,381	93,331	113,456	10,755
	Travelling and subsistence	510,157	1,016,199	350,645	123,408
	Vehicle running costs	1,009,067	1,255,384	364,467	151,874
		26,967,094	**20,122,176**	**13,386,904**	**1,947,858**



		Inflation adjusted		Historical cost	
		AUTHORITY			
Note		2019 ZWL$	2018 ZWL$	2019 ZWL$	2018 ZWL$
18	**Administration expenses**				
	Audit fees	63,274	128,146	19,800	15,000
	Board fees	2,625,024	1,659,944	1,306,939	204,059
	Bank charges	861,303	281,879	367,833	36,090
	Communications	159,308	434,396	64,837	53,735
	Consumables	297,060	354,616	108,270	42,487
	Credit losses	203,701	-	22,379	-
	Credit losses movement	-	-	-	26,416
	Directors expenses	-	172,721	-	21,240
	Depreciation	2,176,455	2,963,483	2,633,556	328,182
	Fair value adjustment	-	4,257,310	-	-
	General administration	1,048,345	895,399	509,356	112,764
	Inspections	5,440,046	1,771,818	2,138,988	211,696
	IT expenses	1,279,400	75,371	742,079	8,635
	Legal and professional fees	504,812	431,038	288,409	56,596
	Printing and stationery	740,380	706,390	434,777	92,762
	Loss on disposal of property, plant and equipment	420,676	-	46,379	-
	Public relations	447,819	643,127	213,930	77,753
	Quality assurance costs	143,830	129,085	42,695	17,788
	Rates, electricity and water	108,204	194,570	52,646	24,306
	Repairs and maintenance	1,819,128	1,246,921	876,415	147,595
	Security and insurance costs	522,161	327,231	273,837	40,643
	Strategic planning	6,227,209	962,229	2,345,046	124,765
	Subscriptions	192,381	93,331	113,456	10,755
	Travelling and subsistence	510,157	1,016,199	350,645	123,408
	Vehicle running costs	1,009,067	1,255,381	364,467	151,874
		26,799,740	**20,000,585**	**13,316,739**	**1,928,549**



Human Capital

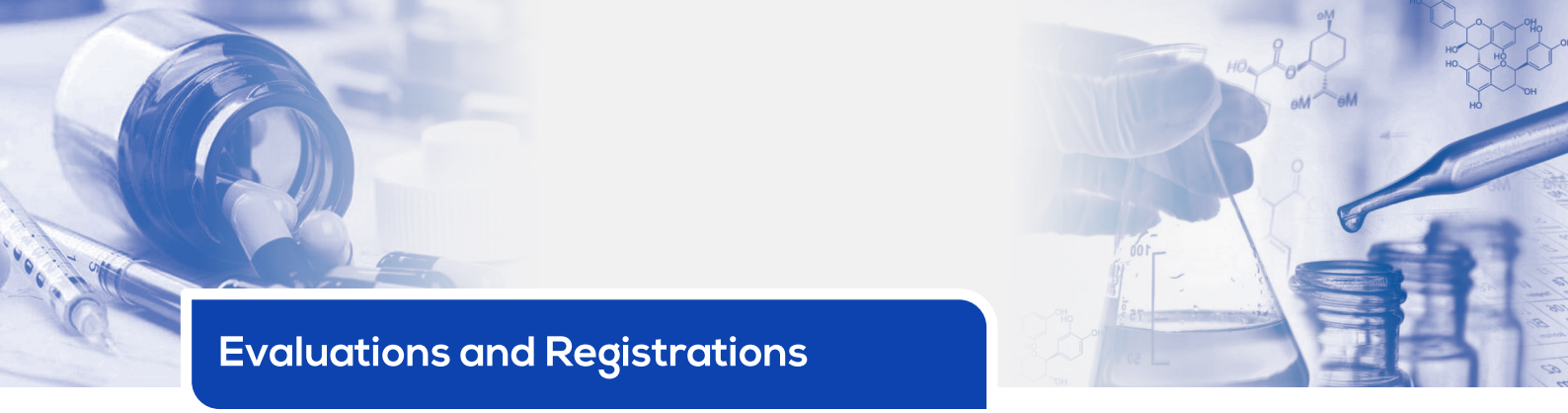
1. As of 31st December, 2019, the Authority's headcount of approved posts was 124 i.e. 72 females (58%) and 52 males (42%).

2. The number of approved posts stood at 141 and 124 were filled (88%) leaving a vacancy rate of 12% i.e. 17 unfilled posts.

3. Out of the 20 approved Managerial positions, 17 were filled i.e. 8 females (47%) and 9 males (53%).

4. In the same period under review, some HR policies under-listed below, were either reviewed or developed to ensure the continued promotion of staff welfare as well as compliance to best practice:
   i) Recruitment (reviewed)
   ii) Study leave (reviewed)
   iii) Training and Development (reviewed)
   iv) Benefits and Schemes (reviewed)
   v) Staff Advancement (reviewed)
   vi) Termination (reviewed)
   vii) Sexual harassment (new)

5. As part of its corporate social responsibility programmes (CSR), the Authority continued to identify and support disadvantaged university students pursuing degree studies in Pharmacy at the University of Zimbabwe and Harare Institute of Technology. In 2019, four (4) students doing either Part II or Part III were recruited. Also, the Authority continued with the recruitment and training of graduate interns (two-year structured training) as well as general (one-year unstructured training).



Evaluations and Registrations

The Evaluations and Registration (EVR) Division has an establishment of a multidisciplinary of team of 28 staff members whose main objective is ensuring quality, safety and efficacy of human allopathic medicines, complementary medicines and veterinary medicines, through document review. The EVR Division also maintains the MCAZ Medicines Registers that are published on the MCAZ website quarterly to ensure manufacturers, wholesalers, pharmacies and the public can verify registration status of products on the market. It also processes WHO-Type Certificate of Pharmaceutical Products (WHO-CPP) as attestations of registration of Zimbabwe products moving across borders in international trade.

Regulatory decision-making by Committees

The Division serves three technical committees: Registration Committee, Complementary Medicines Committee and Veterinary Committee who make statutory decisions on behalf of the MCAZ Board, known as the Authority. Decisions of the Committees are ratified at the Authority's quarterly meetings.

Regional Centre of Excellence

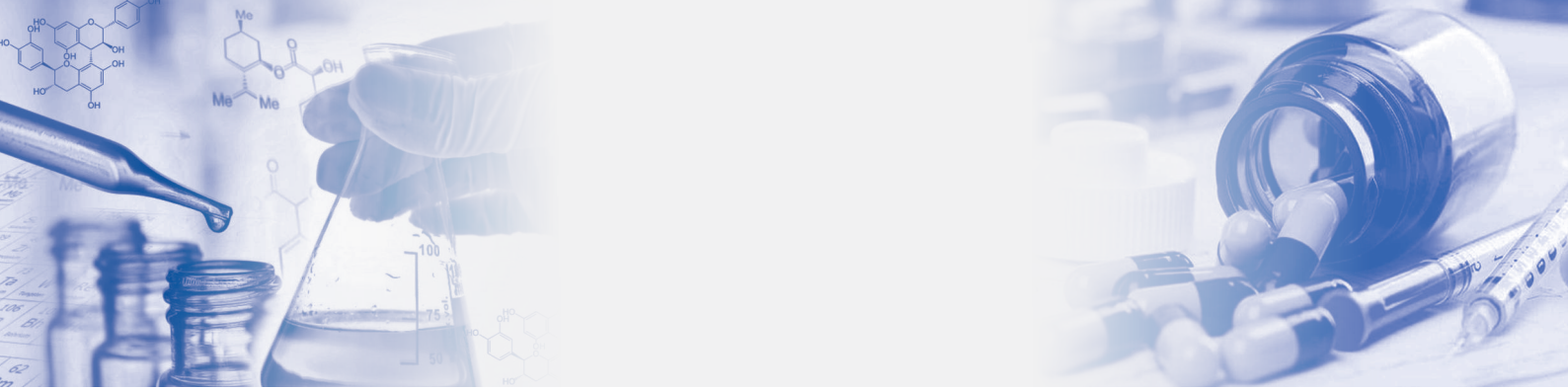
The EVR Division was conferred the Regional Centre of Regulatory Excellence by the African Medicines Regulatory Harmonisation of African Union under the NEPAD in 2011, at the continental level. At the SADC regional level the Division hosts the SADC Medicines Regulatory Harmonisation for registration of medicines. The Division continues to train and provides refresher courses for medicines regulators, regulatory affairs personnel from Zimbabwe, the SADC region and the continent. The training centres on chemistry-manufacturing-and-control (CMC) also known as quality assessment and assessment efficacy of the medicines application files. In 2019 we conducted bioequivalence training, GMP-appreciation for assessors, and evaluation of quality /CMC information. Our ReCoRE programme benefits from the support of the EDCTP grant and technical support.

Human Allopathic Medicines

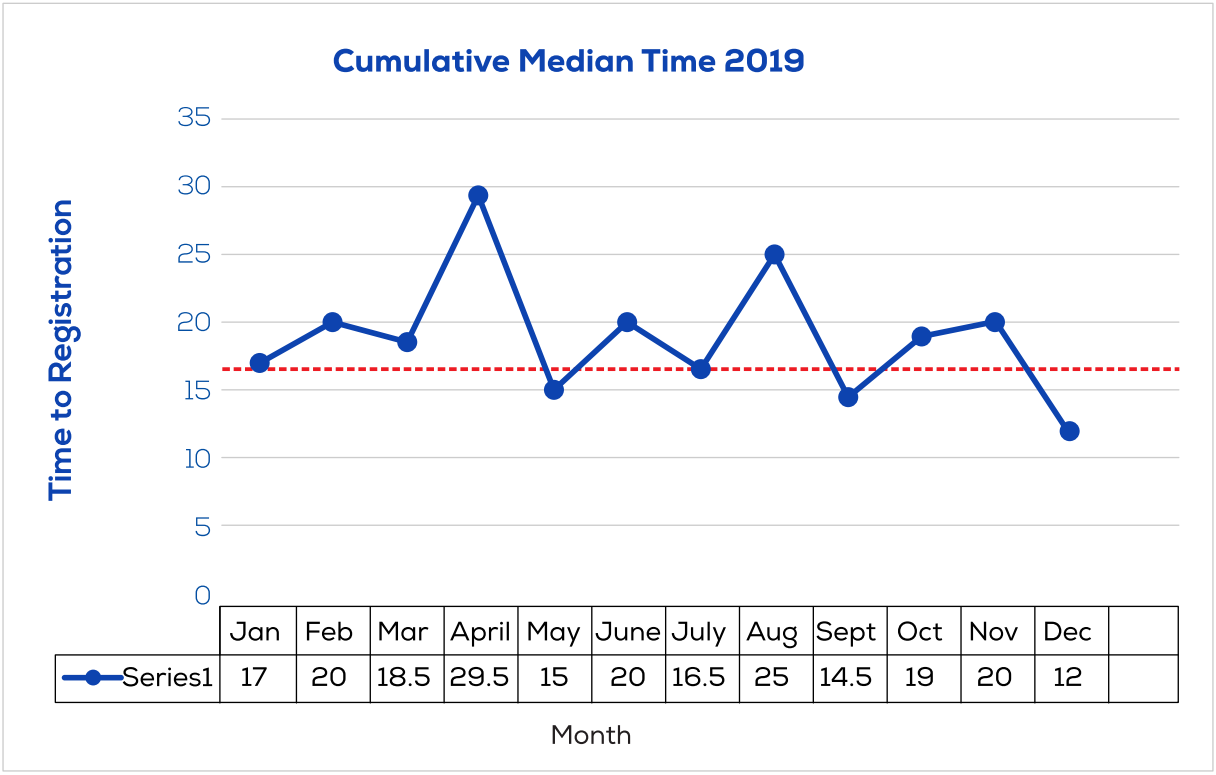
The Human Allopathic Medicines Unit continues to ensure that human allopathic products intended for marketing in Zimbabwe comply with Medicines and Allied Substances Control Act [Chapter 15:03] in terms of safety, efficacy and quality through a rigorous review and approval process. The review process follows the published MCAZ Guidelines for Registration of Products in Common Technical Document (CTD), which incorporate principles from the SADC Harmonisation Registration Guidelines and the WHO Prequalification Guidelines. For novel products whose safety, quality and efficacy may not be well addressed by the above guidelines, MCAZ selectively applies relevant requirements expounded in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines.

Received	Registered	Refused	Withdrawn
195	140	26	21

NB: The applications with a final regulatory decision i.e. registered or refused registration are based on the pool of total pending applications, which includes applications carried over from prior years and those received in the reporting year.



Cumulative Median time to registration for 2019



The overall median timeline to registration (MTR) in 2019 was 563 days 18.75 (15.375-20) months against a target of 16 months. This is inclusive of the manufacturers' time to respond to queries.

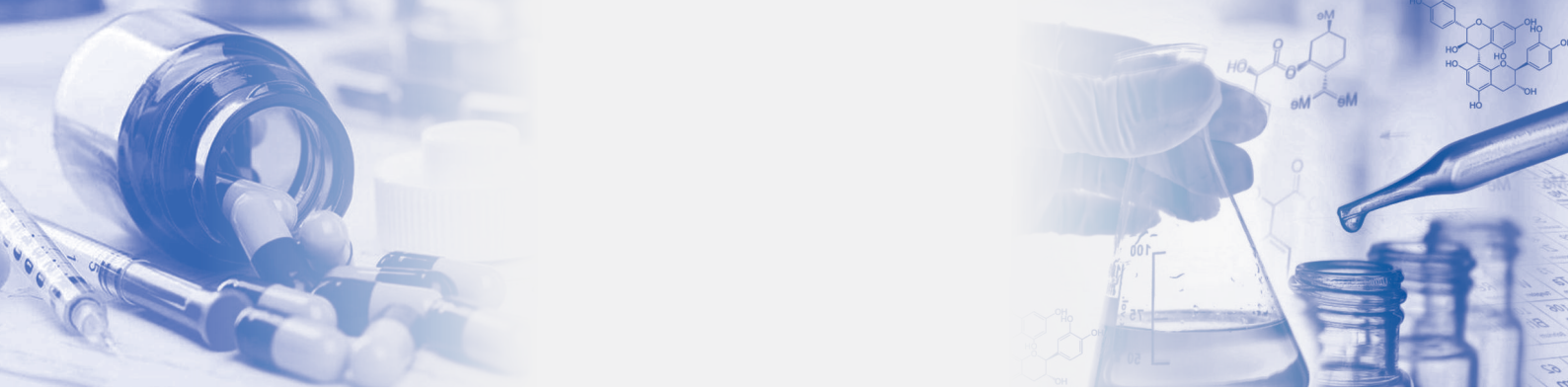
ZAZIBONA work processed in 2019

New ZAZIBONA Applications

Number of new products assessed	Number of products common to Zimbabwe	Number of products assessed by Zimbabwe	Number of products common to Zimbabwe recommended for approval	Number of products common to Zimbabwe recommended for rejection
49	29	7	0	0

ZAZIBONA Response

Number of new responses assessed	Number of products common to Zimbabwe	Number of products assessed by Zimbabwe	Number of products common to Zimbabwe recommended for approval	Number of products common to Zimbabwe recommended for rejection
59	23	14	4	3



Veterinary Products

The Veterinary Unit, comprised of two officers, is responsible for assessing the safety, efficacy and quality of veterinary medicines and issuing marketing authorisation for veterinary medicines. The Unit assesses veterinary medicines for registration making use of the guidelines for registration of veterinary medicines which were derived from the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines. Veterinary vaccines are assessed with separate guidelines, the Guidelines for registration of veterinary vaccines. The MCAZ continued participation at the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Outreach Forum in 2018. The Unit is working on an ongoing basis with other SADC Countries in developing regulatory harmonisation standards for registration of Veterinary Medicinal Products in the SADC Region.

Veterinary Applications 2019

Received	Registered	Withdrawn	Refused	Reinstated
25	20	0	0	1

NB: Application received refers to new applications received, January to December 2019. However, the registered, products included those submitted in prior years.

The Median Time to Registration (MTR) for Veterinary Medicines was 15 (8-24) months against a target of 16 months.

Complementary Medicinal Products

The Complementary Medicines Unit comprised of two dedicated regulatory officers supervised by a Senior Regulatory Officer. Complementary Medicines 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.

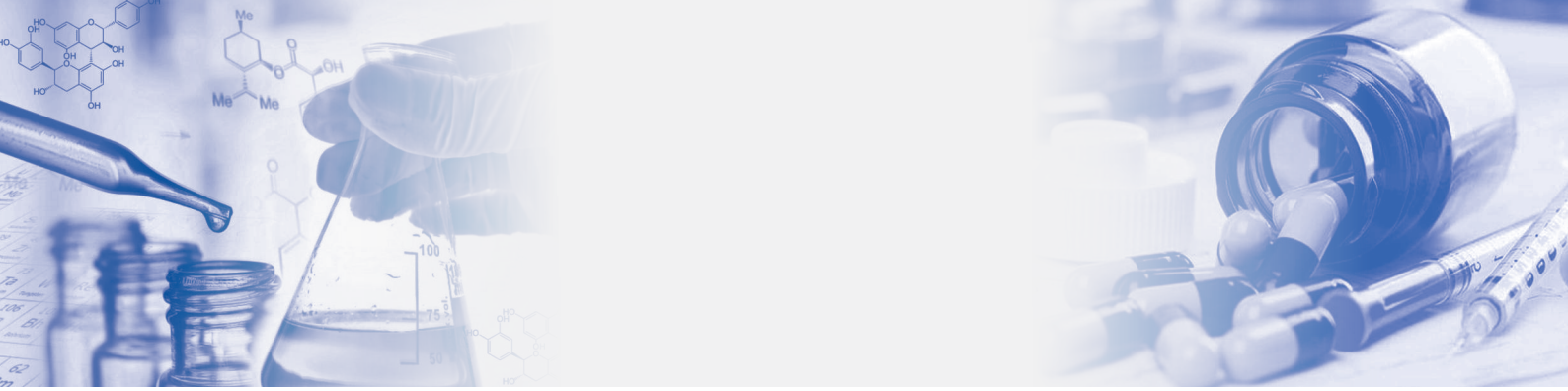
It reports to the Complementary Medicines Committee.

Received	Registered	Withdrawn	Refused
56	187	0	0

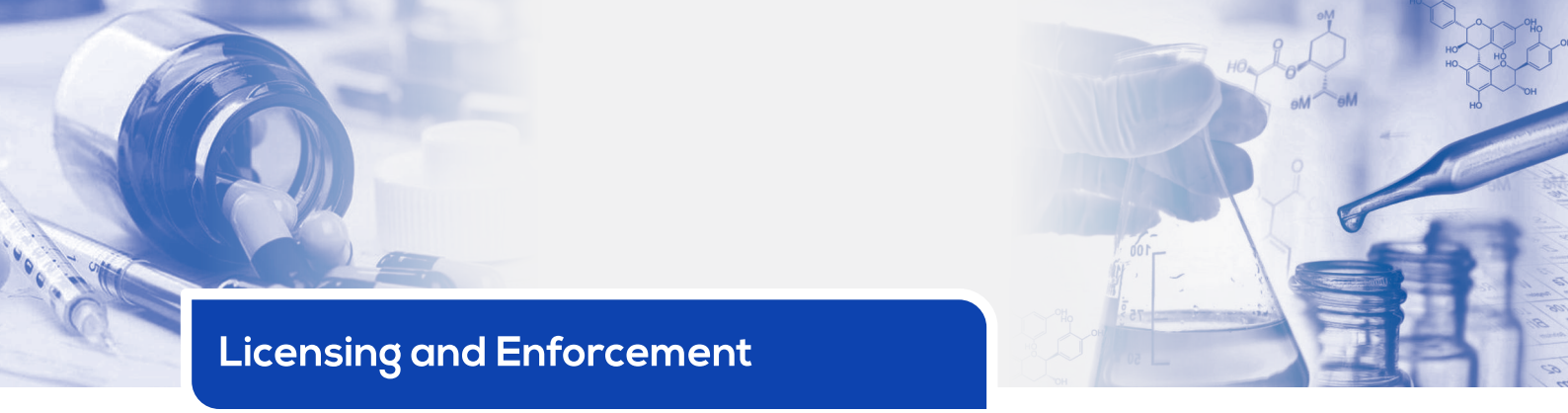
Complementary Medicines

NB: Some of the 187 products approved in 2019 were from the current year and others from prior years.

The Unit managed to arrange a meeting with the Directorate of African Traditional Medicines and the Traditional Medical Practitioners Council to address issues of mutual concern such as evasion of regulatory oversight by people who first register as traditional medical practitioners and then proceed to import and sell foreign herbal and allopathic health supplements and use imported diagnostic gadgets. Concerns were also noted about some unscrupulous traditional medical practitioners who misled the public to believe that they had discovered effective natural cures for HIV/AIDs, cancers, high blood pressure, diabetes and persuaded their clients to default on antiretroviral therapy (ART), cancer, high blood pressure and diabetes treatment and use natural substitute products of unproven efficacy.



The Directorate of Traditional Medicines committed to ensure policy consistence and synergies amongst the Medicines Regulator (MCAZ), the Traditional Medical Practitioner's Council and the Natural Therapist Council to prevent regulated entities from drifting from their licensed domain of practice and mislead unsuspecting patients.



Licensing and Enforcement

In 2019, the Licensing and Enforcement 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

Authorisation for importation of unregistered medicines

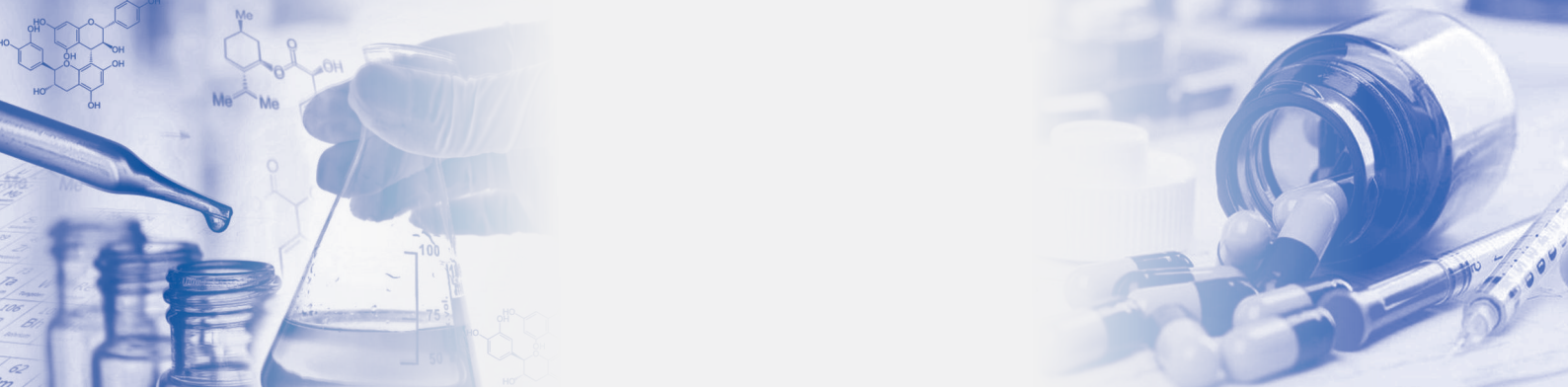
There was a sharp decrease of 56.72% in the number of section 75 applications for individual prescriptions processed from 10178 in 2018 to 4405 in 2019. The number of section 75 applications for institutions increased by 37.87% from 507 in 2018 to 699 in 2019. This can be attributed to the introduction of Circular 4 of 2019 which allowed pharmacies to import medicines in bulk. There was a 16.90% decrease in the number of import permits issued from 1443 in the year 2018 to the 1199 in the year 2019. The number of consignments cleared decreased by 11.45% from 2043 in 2018 to 1809 in 2019. The decrease can be attributed to the challenges wholesale dealers continue to face with regards to acquiring foreign currency.

Administrative issues

Import Permits issued	1199
Number of permits for the importation of precursor substances issued	227
Number of Approved donations for entry into Zimbabwe	282
Number of licenses to import narcotics and psychotropic substances	147
Export permits issued	111
Number of licences to possess, acquire and administer narcotics, including game capture licences	70

Licences and Permits

Pharmacists licences	1137
Pharmacy licences	770
Nurses	383
Veterinary medicines General Dealers' permits	338
Dispensing Medical Practitioners & Veterinary Surgeons	65
Industrial clinics licences	194
Sales Representative Permits	168
Wholesale dealer's permits	108
Pharmacy Technicians	106
Medical practitioner's dispensing licences	56
Manufacturer's licences	11



Enforcement

Inspections conducted in 2019

Following the introduction of the GMP road map for local manufacturers in 2017, inspections were conducted to assess the progress achieved by local manufactures using the GMP road map as the reference point. In the year 2019, 10 facilities against a target of 7 facilities were inspected compared to 7 facilities that were inspected in the year 2018. There was a 9.52% decrease in the number of external manufacturers inspected as 76 blocks were inspected against a target of 80 blocks in 2019 as compared to the 84 blocks that were inspected in 2018.

Two (2) officers were recruited and statistics for 2019 reveal significant improvement in the number of premises inspected for all types of premises against the targets with 142.9% for local manufacturers and 98.17% for Pharmacies which was within the acceptable variance of 10%. There was a 35.71% increase in the number of public institutions inspected from 84 in 2018 to 114 in 2019. There was a 43.20% increase in the number of industrial clinics inspected from 81 in 2018 to 116 in 2019. There was a 78.57% increase in the number of VMGDs inspected from 84 in 2018 to in 2019. 31 wholesalers were inspected in 2018 whilst 54 wholesalers were inspected in 2019.

Regional harmonization and work sharing

MCAZ inspectors participated as lead and co-inspectors during the onsite inspections of 6 blocks out of the 10 blocks that were inspected under the Zazibona collaborative procedure in 2019. Inspectors also participated in the collaborative desk reviews, 11 facilities were assessed which was a 175% increase compared to 2018. MCAZ managers and senior officers participated in the competence assessment of inspectors using the pilot tool developed by WHO. MCAZ was tasked to chair the GMP technical working group which was mandated to develop a SADC GMP guideline.

Good Manufacturing Practices (cGMP)

The GMP inspectorate continued with its quality assurance oversight for both local and international manufacturers through GMP inspections. Most foreign manufacturers marketing their products in the country are under proactive quality assurance scrutiny of the Authority. The approach towards the local industry has been positively aligned towards constructive engagement, to assist the development of local manufacturing of essential medicines. GMP roadmaps continued well during the year with general improvement for most manufacturers especially establishing basic pharmaceutical quality systems. Capacity building GMP Quality Circle trainings continued during the year facilitated by the Authority. Although great potential exists for the local industry to meet global standards, the macro-economic challenges have not spared them, as with many industries in the country.

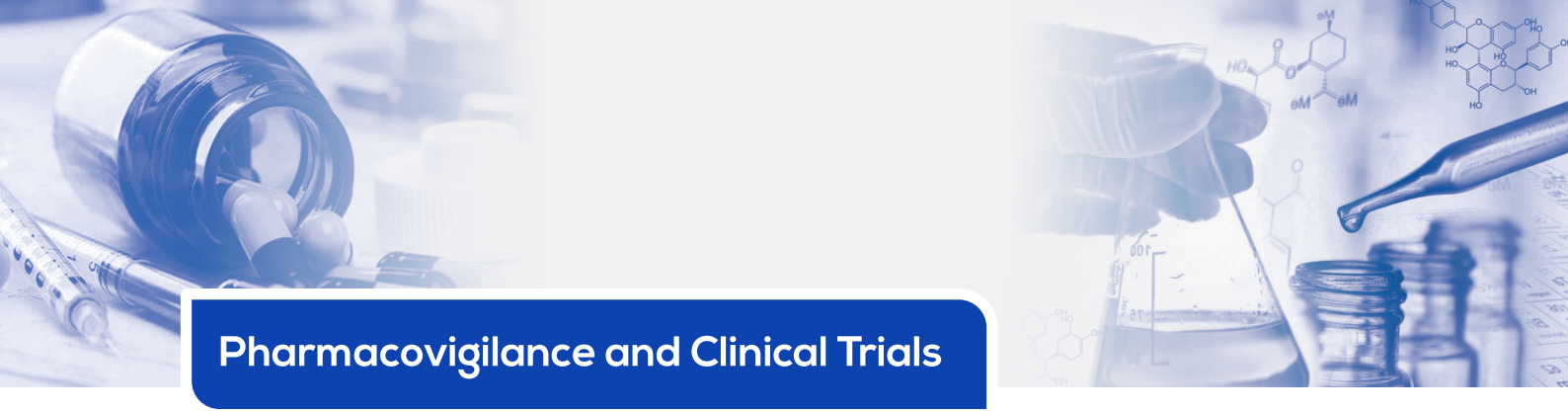
Despite the challenges in the macroeconomic environment, we continue to receive enquiries about how to set up new pharmaceutical plants in Zimbabwe and have since published the GMP guideline on the MCAZ website.

MCAZ GMP Inspections

76 Foreign GMP Inspections
10 Local GMP inspections

Capacity Building Initiatives

2 Quality Circle Workshops were conducted , which aim to promote attainment of acceptable GMP standards amongst local manufacturers, thus promoting local production of quality essential medicines



Pharmacovigilance and Clinical Trials

As the National Centre for Pharmacovigilance and an official member of the WHO Programme for International Drug Monitoring, a total of 496 Individual Case Safety Reports (ICSRs) were received in 2019, this was 13% lower than the number of reports received in 2018 (571). This may be attributed to less number of pharmacovigilance trainings conducted in 2018 due to limited funding. Feedback was provided to the health care practitioners through written letters, presentations at the pharmacovigilance workshops, site visits and through the medicines bulletin published. All the reports received in 2019 were uploaded onto the WHO Vigibase® database.

Reports received in 2019 are highlighted in the table below.

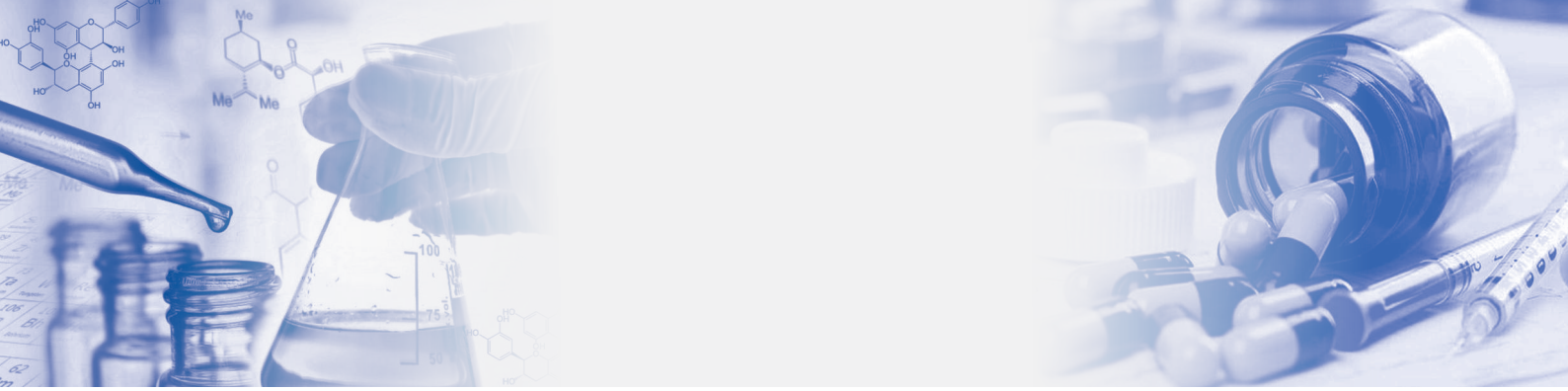
Table 1. Individual Case Safety Reports received in 2019

Type of report	Number of Reports Received
ADRs and Serious Adverse Events (SAEs) received from pharmaceutical industry	118
SAEs from approved Clinical Trials conducted in Zimbabwe	103
Adverse Events Following Immunization (AEFIs)	83
ADRs from the Targeted Spontaneous Reporting (TSR) of all essential medicines including ARVs and Anti-TBs from public MoHCC sites and some private sector clinics and doctors	173
Electronic ADR reports from the TSR of all essential medicines including ARVs and Anti-TBs from public MoHCC sites and some private sector clinics and doctors	19
TOTAL	**496**

Targeted Spontaneous Reporting (TSR) program for ARVs, anti-TB and other essential medicines

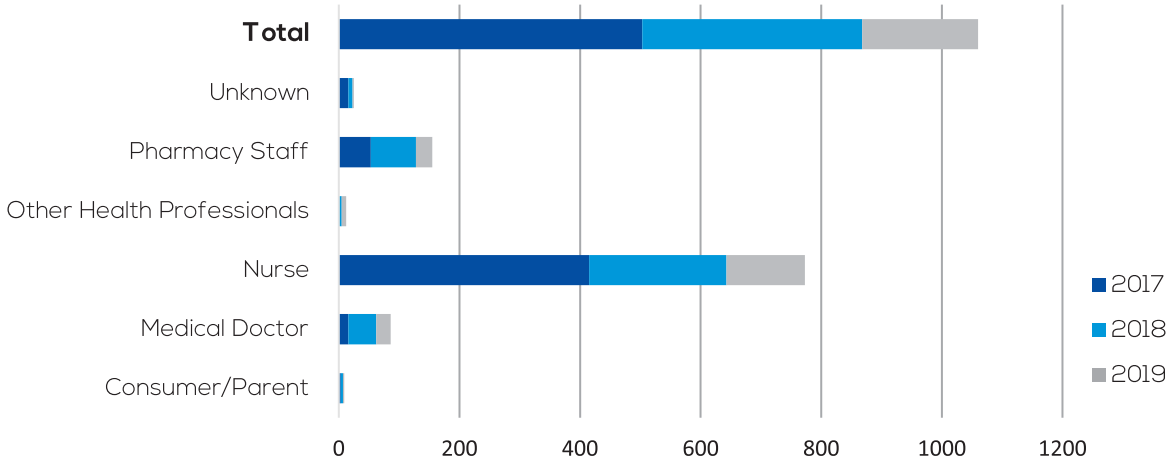
The Targeted Spontaneous Reporting (TSR) Program for ARVs, anti-TBs and other Essential Medicines has been running successfully and has seen an increase in the number and quality of Adverse Drug Reports (ADR) that have been received by the MCAZ.

A total of 1050 health care professionals were trained from 2012 to 2019 in all provinces. The aim of the trainings was to educate, encourage and remind all health care professionals to continuously participate in the reporting of ADRs and preparation for the establishment of regional pharmacovigilance sites. In 2019 a total of 5 pharmacovigilance trainings were conducted in Harare, Matabeleland South, Mashonaland Central and Manicaland. 2 trainings were done in Harare. A total of 102 healthcare professionals were trained in the five provinces, Harare (26), Matabeleland South (28), Mashonaland Central (20) and Manicaland (28). Among the healthcare professionals trained in 2019, 16 were doctors, 43 pharmacy staff, 33 nurses and 10 others.



The figure 1 below indicates the total number of TSR reports received by the MCAZ and the reporting professionals from 2017 to 2019.

Figure 1: Cumulative distribution of reports by reporting professional and period recieved by the MCAZ



	Consumer/ Parent	Medical Doctor	Nurse	Other Health Professionals	Pharmacy Staff	Unknown	Total
2017	3	16	415		53	16	503
2018	4	46	228	5	75	7	365
2019	2	24	130	7	27	2	192

The graph shows that the majority of reports in 2017, 2018 and 2019 were reported by nurses. This shows that nurses continue to be the leading reporters for adverse drug reactions. All the reports were evaluated for causality assessment by the PVCT Committee and reporters were sent feedback on the assessments. The feedback on the TSR was also included in the 2019 bulletin as a way of disseminating information obtained from the reports. The graph below shows the trend of healthcare professionals trained and the number of reports received. As shown in the graph the number of adverse drug reaction reports received increases as the number of healthcare

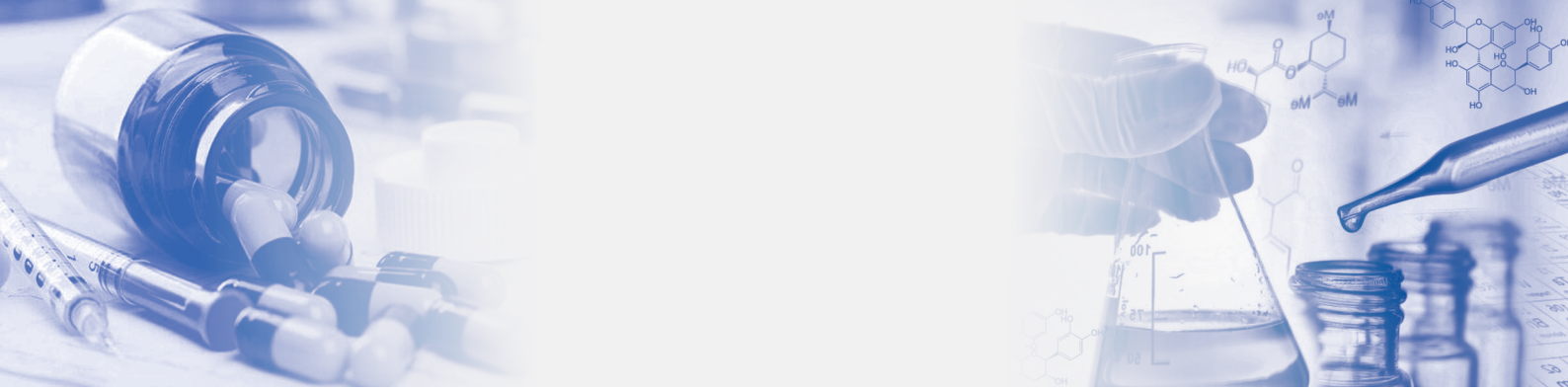


Table 2. Comparison by province of reports received by MCAZ

Reporting Province	2017	2018	2019	Total
Bulawayo	35	100	49	184
Chitungwiza	38	0	14	52
Harare	74	31	52	157
Manicaland	6	136	8	150
Mashonaland Central	129	41	31	201
Mashonaland East	8	1	5	14
Mashonaland West	13	9	1	23
Masvingo	4	0	1	5
Matebeleland North	126	0	5	131
Matebeleland South	4	32	12	48
Midlands	62	4	9	75
unknown	4	11	5	18
Total	**503**	**365**	**192**	**1058**

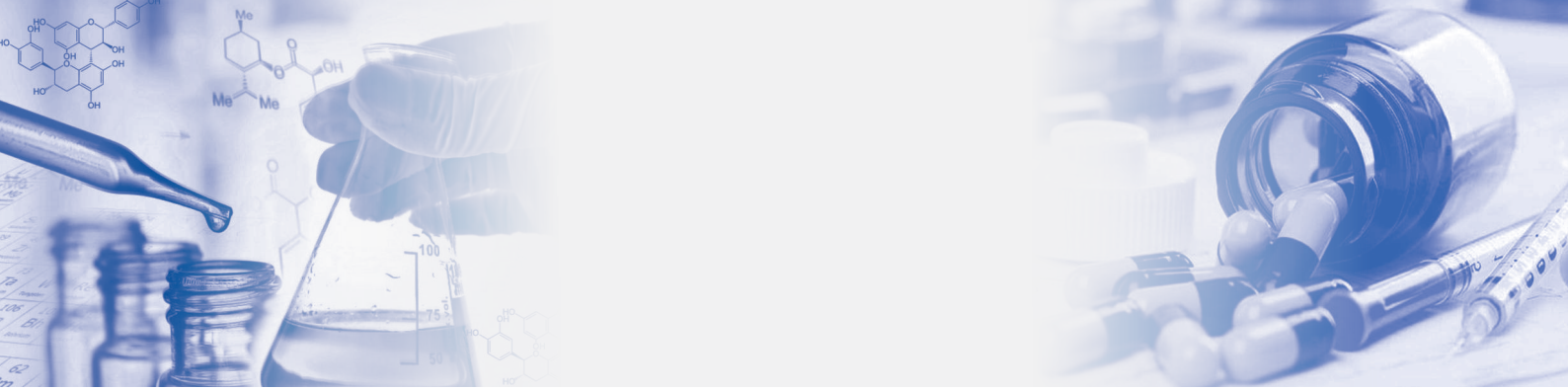


Table 2 shows that Harare province contributed the highest number of reports in 2019, whilst Masvingo and Mashonaland West contributed the lowest number of reports. This may be due to the two Pharmacovigilance Trainings that were conducted in Harare. in 2019. As a way forward, the Authority would prioritise provinces with low number of reports for pharmacovigilance visits and trainings in 2020.

Pharmacovigilance Regional Centers

In an effort to improve the pharmacovigilance system in Zimbabwe, in 2017 during TSR trainings the MCAZ discussed with health professionals which included Provincial Medical officers, Provincial Nursing officers, Provincial Pharmacists, District Medical officers and District Nursing officers in all the 10 provinces on how to set up pharmacovigilance centers. It was agreed during these trainings that the provincial pharmacists would be the provincial pharmacovigilance focal persons in liaison with all the MoHCC protocols. Following review of the Terms of References, these would be circulated for review by all stakeholders and partners such as the Ministry of Health, AIDS and TB Unit and Department of Pharmacy Services in 2020. In December 2019 a request from Harare hospital to be included as a pharmacovigilance sentinel site was received. The setting up and formalization of these centres is in progress and is expected to be finalised in 2020.

Electronic Adverse Drug Reaction 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 are expected to increase efficiency and ease of doing business for both the internal staff and external customers. The e- systems were launched in 2019. Stakeholders were notified of these new developments through circulars. E-ADR system was presented at AiBST Symposium, ART &TB & ZNFPC forums in April and August 2019. Dissemination of these electronic systems was also done during pharmacovigilance workshops and monitoring visits and other various forums. 19 reports had been received through the e-ADR platform by end of 2019.

Regulatory Centre of Excellence (RCORE) Training in Clinical Trials Regulatory oversight

As part of the Regional Centre of Regulatory Excellence (RCORE) in Clinical Trials initiatives, MCAZ in partnership with the Medicines Research Council of Zimbabwe (MRCZ) have designed an intensive course to build capacity and equip other regulators in Clinical Trials. The course is designed to promote harmonization in regulatory requirements. The objective of this course is to train and equip participants with the requisite knowledge and skills to enable them to evaluate and review clinical trial applications and effectively monitor ongoing clinical trials. As part of the RCORE activities in 2019 the division conducted 1 RCORE training in Clinical Trials Regulatory oversight. Five (5) participants from Namibia, 1 from Namibia Medicines Regulatory Council and the other four from Namibia Ministry of Health and Social Services attended the training. The participants were hosted at the MCAZ for two weeks and were exposed to different aspects of clinical trials being done by the Authority and the MRCZ.

MedSafety Week

The MCAZ participated in the fourth annual MedSafety Week, where medicine regulatory authorities across the world took part in a social media campaign to raise awareness of medicine side effects, and the importance of reporting them. MedSafety Week is a joint effort between 57 medicine regulatory authorities across the globe. This campaign forms part of a global initiative led by Uppsala Monitoring Centre (UMC) – the World Health Organisation (WHO) Collaborating Centre for International Drug Monitoring in collaboration with the Heads of Medicines Agencies (HMA) and the International Coalition of Medicines Regulatory Authorities (ICMRA). The 2019 campaign focused on polypharmacy, with the overarching message that reporting side effects helps protect patients when taking multiple medicines.

Vaccine Safety Issues

Global Vaccine Safety Multi-Country Collaboration (GVS MCC) Project

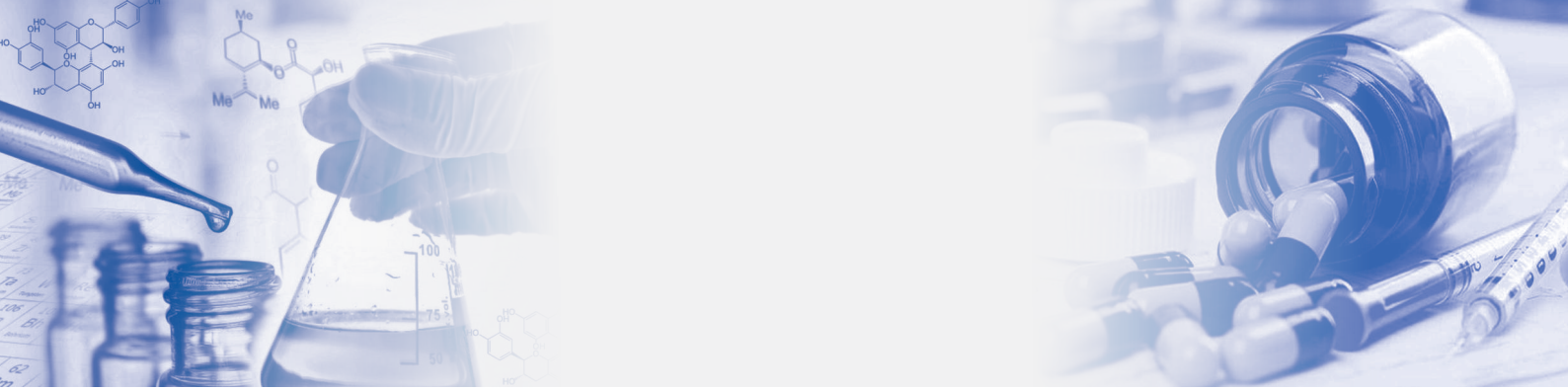
The WHO with support from P-95 (Belgium) and International Clinical Epidemiology Network (INCLEN, India) initiated the Global Vaccine Safety Multi-Country Collaboration (GVS MCC) project. The objective of the study is to measure the risks of early childhood morbid conditions and assessing the applicability of standardized case definitions to inform future vaccine safety studies. The study is being conducted across 22 sites in 7 countries, including two sites in Zimbabwe namely Mutare Provincial Hospital and Edith Opperman Maternity Hospital in Mbare,. The role of MCAZ was to provide support in the identification of the study sites and also conducting GCP monitoring visits. In 2019 two GCP monitoring visits were conducted at these Zimbabwean sites. An officer from MCAZ was also part of the monitoring team that visited the two sites in Ghana and was trained on how to conduct GCP monitoring.

Typhoid Conjugate Vaccination Program

The division evaluated the Typhoid Conjugate Vaccination Campaign Safety Monitoring protocol and provided recommendations to the Centers for Disease Control (CDC) and MoHCC. The PVCT officers together with staff from CDC, WHO and MoHCC facilitated a two day training of healthcare workers on AEFI management before the vaccination campaign in 2019. The National AEFI Committee attended a refresher training on causality assessment of AEFI reports which was facilitated by the WHO. The Committee then conducted causality assessment for the 49 AEFI cases that were received for the TCV Campaign and provided feedback to the MoHCC.

Vaccine Safety Net Project (VSN)

Since its establishment in 2003, Vaccine Safety Net (VSN) has facilitated easy access to reliable, understandable, evidence-based information on the safety of vaccines for internet users, regardless of their geographic location and language.



MCAZ participated in the project and the web page with Vaccine safety information was created on the MCAZ website. The MCAZ website was assessed by the WHO and recommendations to be addressed were made. The Authority is expected to be a member of the VSN by 2020 after addressing all the recommendations made and the MCAZ website will be listed on the WHO website and the VSN portal.

Stimulated Telephone Assisted Rapid Safety Surveillance (STARSS) (II) randomized trial assessing Adverse Events Following Immunisation (AEFIs).

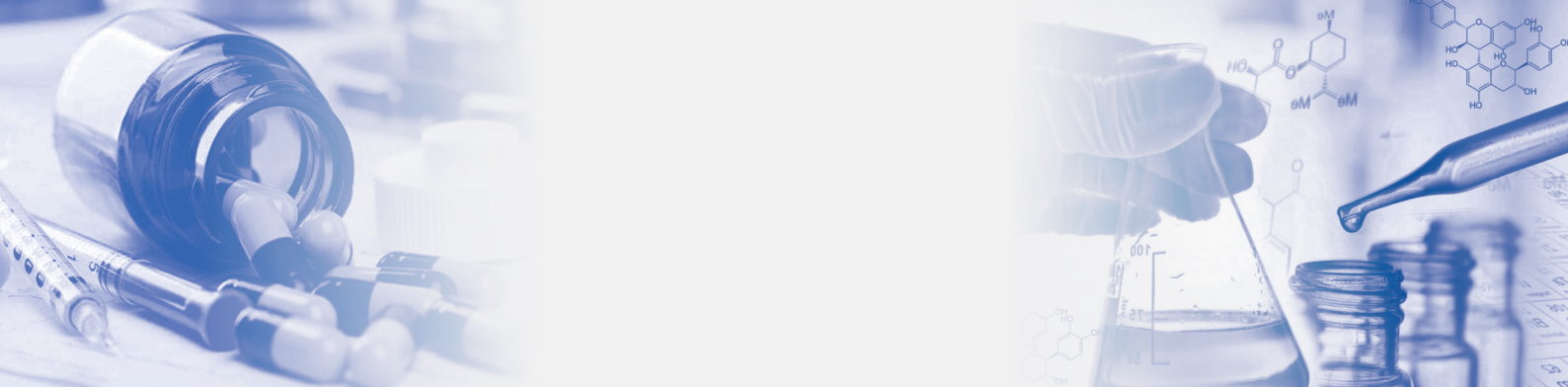
The use of e-health to improve post-marketing surveillance of vaccines in Zimbabwe. A case study of Stimulated Telephone Assisted Rapid Safety Surveillance (STARSS) (II) randomized trial assessing Adverse Events Following Immunisation (AEFIs).

The STARSS study is a mobile Health technology designed to detect serious AEFIs early so that risk assessment, management, mitigation and communication may be done to promote patient safety. Similar technology was successfully used in Australia. The study will be conducted in Zimbabwe in 2020 to demonstrate proof of concept of the STARSS technology, AEFI active surveillance innovation in Low to Medium Income Countries settings. A total of 4,500 infants and children will be recruited from the study sites that have the capacity for hosting the software. The STARSS study protocol approval was granted permission by the Secretary for Health and Child Care to be conducted by MCAZ in collaboration with Zimbabwe Expanded Program on Immunisation (ZEPI) and the vaccination clinics. Ethical approval of the study protocol was granted by the Medical Research Council of Zimbabwe (MRCZ). Funding and technical support is provided by WHO.

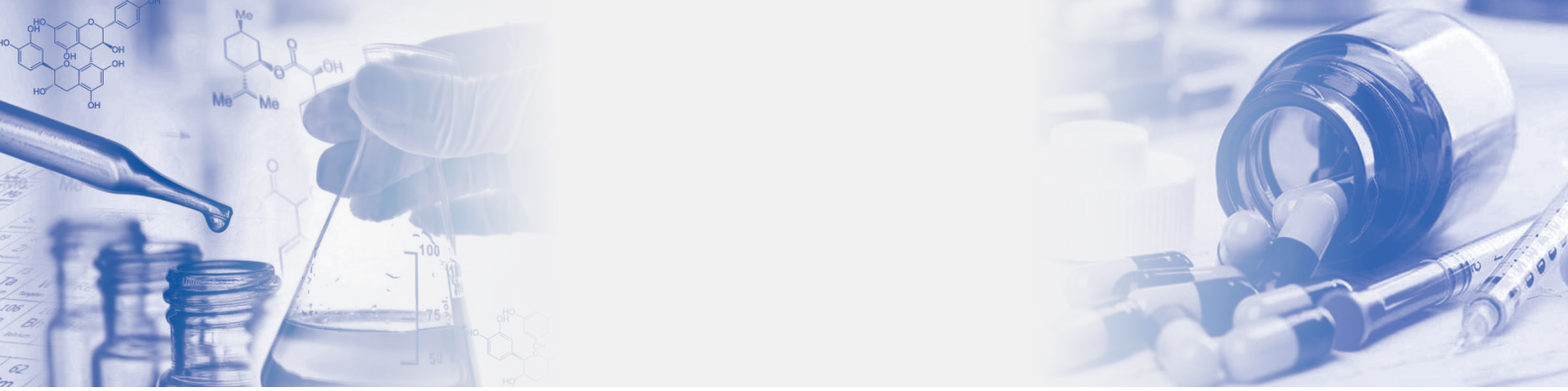
Medicines Safety Reviews Conducted in 2019

In 2019 the division conducted a number of medicine safety reviews as shown below.

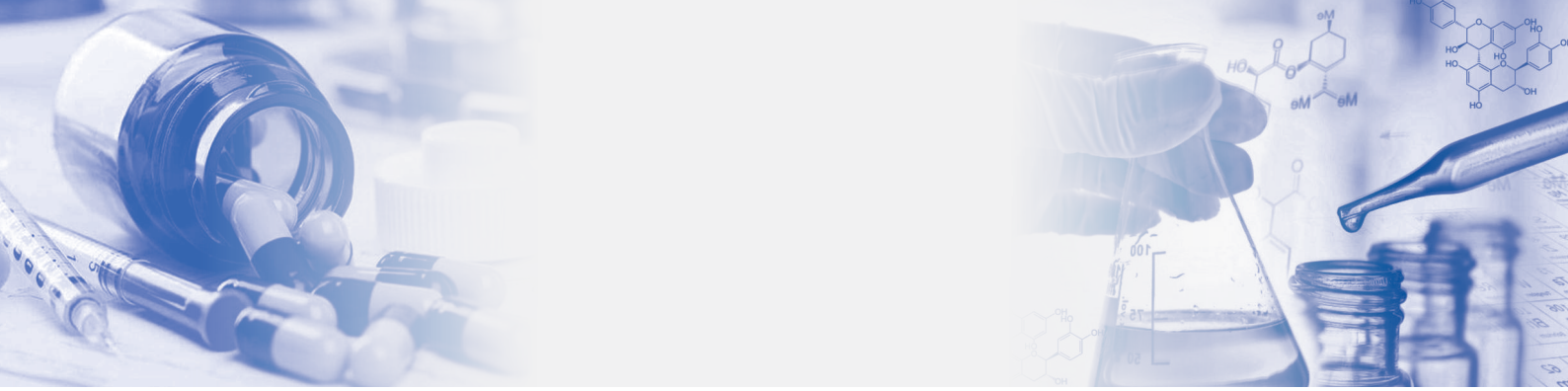
Product(s)	Description of the Safety Concern	Recommendations Made
Tartrazine Ponceau 4r	They were gazetted as undesirable substance in pharmaceutical products due to safety concern mainly hypersensitivity reactions.	Tartrazine and Ponceau 4r were found to be safe in pharmaceutical products according to the recent safety information reviews and studies. It was recommended to repeal these two ingredients from the list of undesirable substances in the Medicines and Allied Substances Control Regulations (SI 150 of 1991 and S1 97 of 2015) Fifteenth Schedule (Section 77a) Complementary Medicines Regulation SI 97 of 2015 seventh Schedules Section 22
Undesirable substances in Pharmaceutical Products;	Following the full safety review of Tartrazine it was recommended by the MCAZ Registration and Pharmacovigilance & Clinical Trials	Safety reviews were done and the recommendation was that these substances should continue to be on the list of undesirable substance in



Product(s)	Description of the Safety Concern	Recommendations Made
Astemizole Benoxaprofen Chlormezanone Clioquinol Dipyrone Lead and lead salts Nimesulide Oxyphenbutazone Phenacetin Phenformin Phenolphthalein Practolol Rofecoxib Zomiperac Chloroform Chlorofluorocarbons	Committees that the list of ingredients gazetted as undesirable substance in pharmaceutical products due to various safety reasons should be reviewed to update the list in line with current safety information.	pharmaceutical products since they were still unsafe to be used in pharmaceutical products and banned in several countries.
Dextropropoxyphene	The product has been taken off the market in Europe and the US and other countries due to concerns of fatal overdoses and heart arrhythmia. The product was withdrawn from the market by MCAZ in 2012 for the same safety reasons mentioned above.	Inclusion of Dextropropoxyphene on the list of undesirable substances in the Medicines and Allied Substances Control Regulations (SI 150 of 1991 and S1 97 of 2015) Fifteenth Schedule (Section 77a), Complementary Medicines Regulation SI 97 of 2015 seventh Schedules Section 22
Fluoroquinolone and Quinolone Antibiotics	i. Resistance ii Serious, disabling and potentially permanent side effects which includes tendonitis, tendon rupture, arthralgia, pain in extremities, gait disturbance, neuropathies associated with paraesthesia, depression, fatigue, memory impairment, sleep disorders, and impaired hearing, vision, taste and smell.	A circular was written to healthcare professionals informing them of these safety concerns and warnings. Healthcare professionals were also encouraged to use this group of antibiotics where it is necessary and to monitor these reactions and report to MCAZ should any adverse drug reactions occur.
Tetrahydrocannabinol-free Cannabinoid-containing products	A request was received from the Evaluations and Registration Division for safety review of Tetrahydrocannabinol-free Cannabinoid-containing products. They had received enquiries on the registrability of Cannabinoid-	It was agreed that there was insufficient safety data and experience from other stringent countries as very few products have been registered by other countries. Therefore the products should continue to be treated as Dangerous



Product(s)	Description of the Safety Concern	Recommendations Made
	containing supplements and the Complementary Medicines Sub-Committee noted that nowadays there are several cannabidiol containing products that are claimed to be free of the main psychoactive component in cannabis; Tetrahydrocannabinol (THC). The Complementary Medicines Sub-Committee therefore recommended that EVR seeks guidance from the PVCT on the safety of THC-free cannabidiol containing products before making a final recommendation on the registrability of these products as complementary medicines	Drugs with restricted sale as stipulated.
Metoclopramide	Signal of visual disturbances and oculogyric crisis	Applicants were required to update their product information to include this side effect
Proton Pump Inhibitors Omeprazole, Pantoprazole, Esomeprazole Rabeprazole Lansoprazole	Signal of possible association of the use of proton pump inhibitors and the risk of myocardial infarction.	Applicants were asked to comment on the safety issue.
Salbutamol oral	Benefit- risk profile was perceived to be negative therefore benefit risk analysis was conducted.	It was agreed to make HCP aware of the safety issues associated with oral salbutamol and the recommendations made in the EDLIZ and the WHO guidelines which recommend that salbutamol oral preparations should not be used.
Ranitidine	Potential contamination with Nitrosamine impurities which are probable human carcinogens.	Applicants of Ranitidine containing products were required to comment on the possibility of contamination of their products with Nitrosamine impurities and carry out the appropriate investigations



Pharmacovigilance Monitoring Visits.

Pharmacovigilance monitoring visits in 4 provinces namely, Mashonaland East, Mashonaland West, Manicaland and Mashonaland Central were conducted. A total of 40 health facilities were visited which included provincial hospitals, district hospitals, rural health centres and clinics.

The following were the main objectives of the visits;

- **i.** Sensitization of healthcare professionals on Pharmacovigilance
- **ii.** To provide feedback on the PV projects being conducted by MCAZ and on Adverse Drug Reactions (ADRs) reported to MCAZ over the years
- **iii.** Formalization of pharmacovigilance provincial and district centres
- **iv.** Dissemination of information on the new MCAZ e- ADR reporting platform
- **v.** To encourage health care professionals to report ADRs and to be part of Targeted Spontaneous Reporting of ARVs and Anti-TBs and to provide feedback on the TSR project
- **vi.** To encourage AEFI reporting and case investigation
- **vii.** To distribute and collect completed forms

Medicine Information Bulletin

The division managed to publish a medicine information bulletin in October 2019. The main topics in the bulletin included the following; E-Reporting Tools, Safety Notifications for Fluoroquinolones and Quinolones Antibiotics, Notification of a potential risk of non-melanoma skin cancer (basal cell carcinoma, squamous cell carcinoma) in patients treated with hydrochlorothiazide, DTG and Neural tube defects and Dangers of buying medicines from the streets. The medicine information bulletin was distributed through various channels to all the relevant stakeholders. The Medicines Information Bulletin is available on MCAZ website and is accessible on the following hyperlink:
http://www.mcaz.co.zw/images/pdf/Medicines_information_bulletin_Vol_1_October_2019.pdf.

Circulars and Alert notices

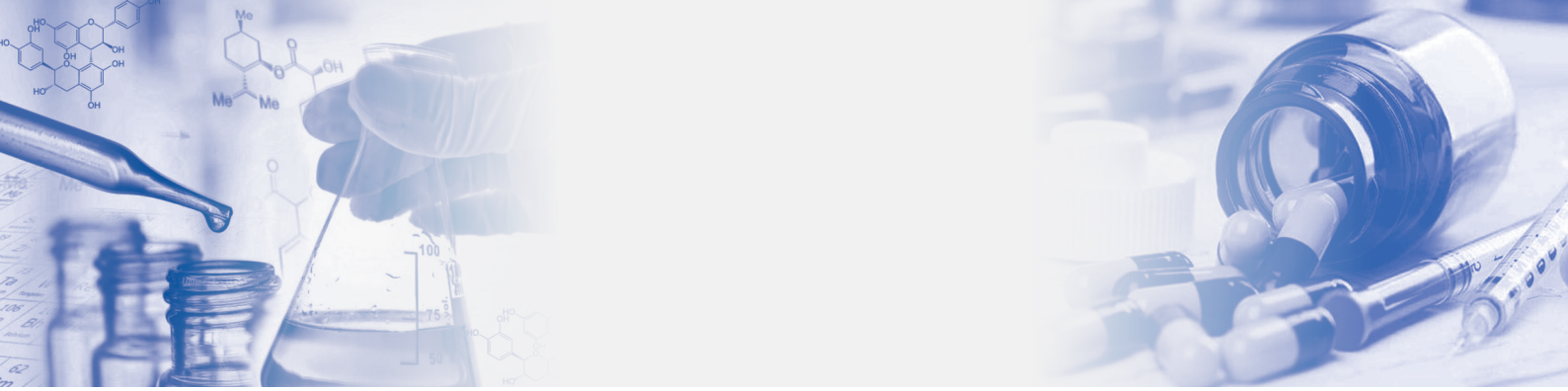
The division issued 2 circulars in 2019 communicating medicines safety to health care professionals as shown below:
Circular 1 of 2019 - Notification of Potential Risk of Non-Melanoma Skin Cancer in Patients Treated With Hydrochlorothiazide

1. Circular 7 of 2019 - Safety Notifications for Fluoroquinolones and Quinolones Antibiotics
2. Serious low blood sugar levels and mental health side effects associated with fluoroquinolones antibiotic

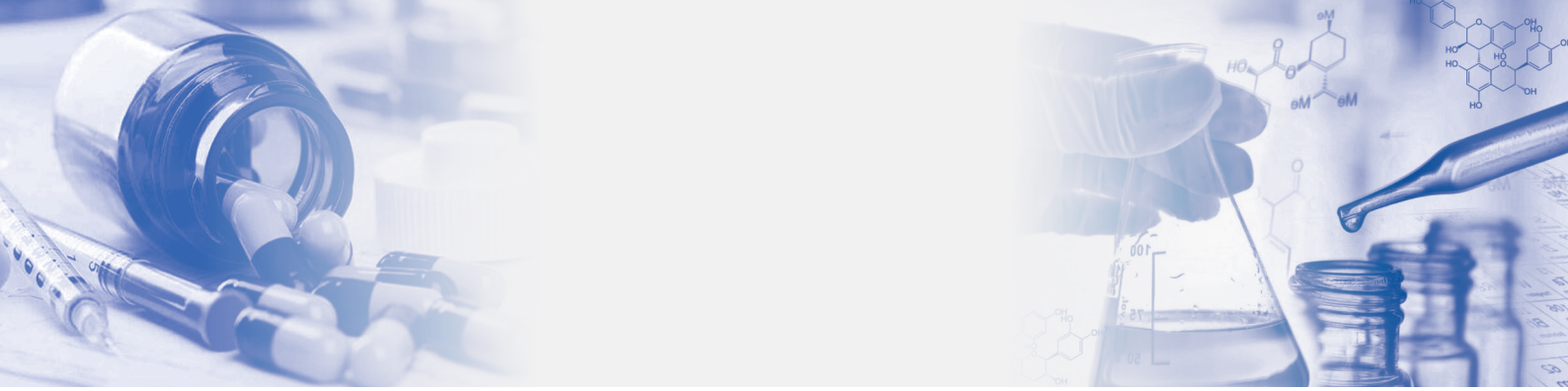
Post Registration Activities

Changes of Category for Distribution of Medicines

The PVCT Division is also responsible for processing of applications for changes of category for distribution of medicines. In 2019, 4 applications for re-categorisation were processed and 3 of them we approved and one was refused. Letters to the applicants to this effect were written.



Generic Name	Proposed Change	Justification Provided	Decision made
Lansoprazole 30mg containing oral products Esomeprazole 20mg containing products Rabeprazole containing products Pantoprazole Sodium 20mg Tablets	Prescription Preparations (P.P) to Pharmacist Initiated Medicine	The products are indicated for Gastroesophageal Reflux Disease (GERD). GERD can be diagnosed based on history of signs and symptoms and pharmacists can easily diagnose it. Indirect danger may arise by masking any serious underlying conditions such as an upper gastrointestinal tumour and therefore treatment by the pharmacist should be limited to a maximum of 2 weeks. The safety and tolerability of esomeprazole and other proton pump inhibitors is well-established and is supported by post-marketing experience. The products are available as general sales in other countries.	Approved
Mepyramine maleate 2% topical cream	Pharmacy medicine to Household Remedy	To provide the consumers with access to the cream at more convenient time and location. Due to the nature of the indication of the product it is most likely that consumers may need the product during weekends or at remote areas where they are more prone to insect bites and stings. The classification change will enable patients to get the medicine faster and easier. This is crucial as early application of the medicines is essential to obtain optimum response. Topical mepyramine is also available as General Sale in other countries such as is equal to HR in the UK, Canada, USA and New Zealand. The safety and efficacy of topical mepyramine are well established and side effects are rare.	Approved



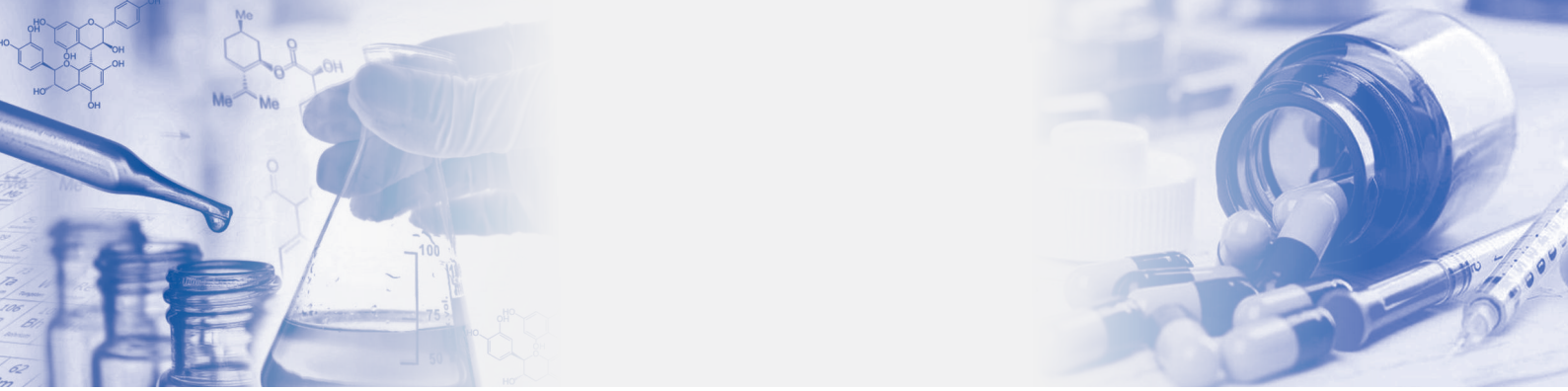
Generic Name	Proposed Change	Justification Provided	Decision made
Flurbiprofen 8.75mg Lozenges	Pharmacy-only medicine (P) to House Hold Remedy (HR)	Pharmacy operating hours are generally short compared to operating hours of supermarkets. This can limit the access of patients to required medication. The reclassification of Flurbiprofen 8.75mg Lozenges to General sales medicines will allow patients easier and more convenient access to an effective and short term therapy.	Rejected. The Committee agreed that the current category for distribution remains appropriate as unsupervised sales would pose unnecessary risk to the public due to the nature of the dosage form particularly for use by children, in individuals with pre-existing health conditions and interactions with concomitant medicines. A similar reclassification application had been rejected in Australia.

Applications for Safety variations and Promotional Materials

55 applications for safety variations and 21 promotional materials were received and processed in 2019.

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, 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.



Highlights

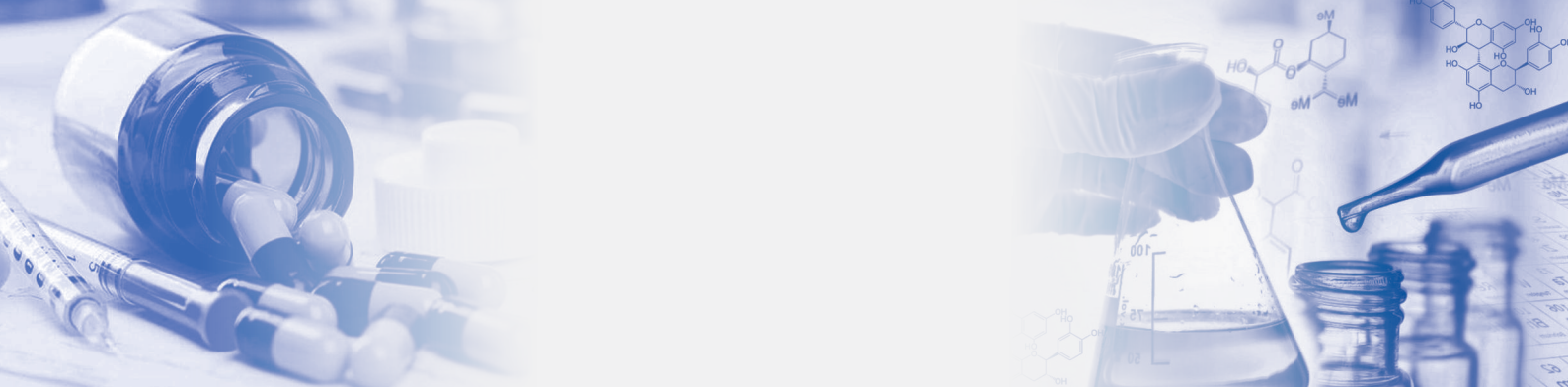
Foreign Products **94%** IN 2019 VS. **94%** IN 2018	**Payment of Retention Fees**	Foreign Products **93%** IN 2019 VS. **90%** IN 2018
Local Products **81%** IN 2019 VS. **76%** IN 2018		Local Products **84%** IN 2019 VS. **99%** IN 2018
HUMAN MEDICINES		VETERINARY MEDICINES
2560 IN 2019 VS. **2033 IN 2018**		**310 IN 2019** VS. **351** IN 2018
55 IN 2019 VS. **18** IN 2018	**Cancelled Products**	**4** IN 2019 VS. **19** IN 2018

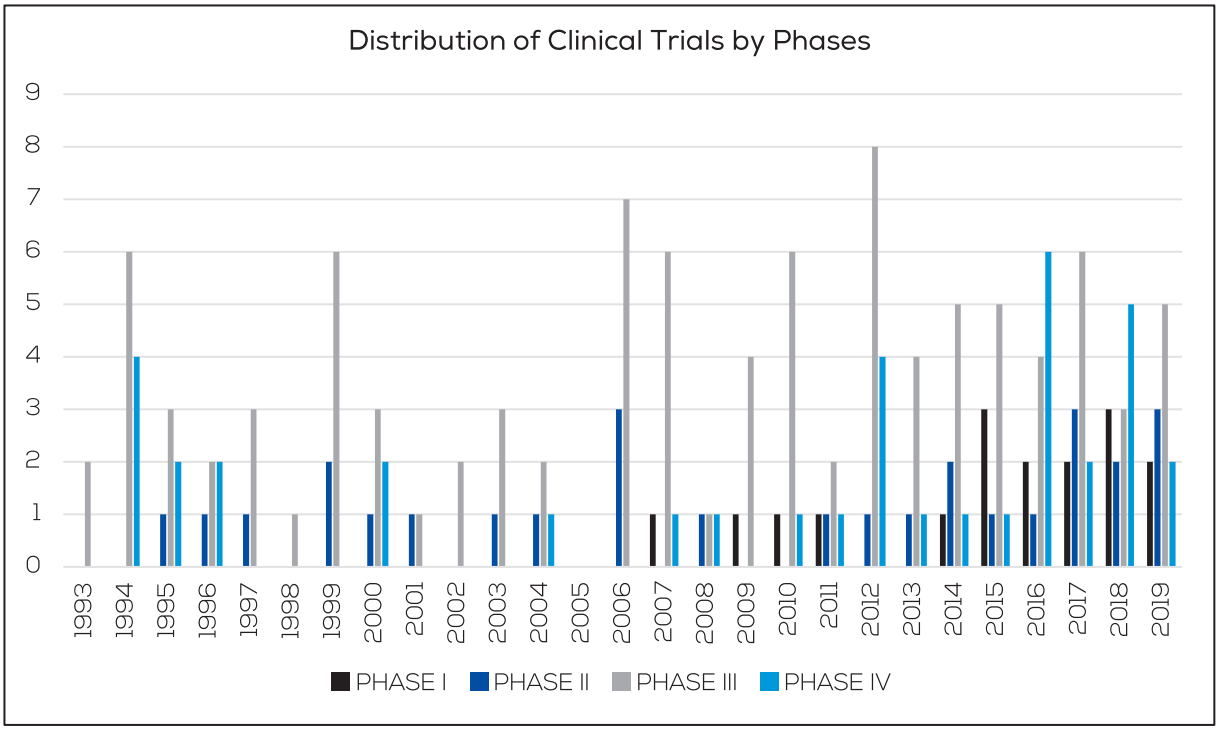
As highlighted above there was no change in collection of retention fees in 2019 for human foreign products as compared to 2018. However there was an increase in retention fees collected for Veterinary foreign products and Human Local products in 2019. There was a decrease in retention fees collected for veterinary local products in 2019 as compared to 2018 and this may be due to the economic challenges faced by the local companies.

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. In 2019, 5 officers attended a GCP training offered by the University of Zimbabwe College of Health Science, Research Support Centre. 3 officers also completed an online GCP training funded by the National Institute of Health and they were awarded certificates. 4 routine GCP inspections were also carried out in 2019. The purpose of the inspections was to ascertain GCP compliance of the approved studies.

12 clinical trial applications were received in 2019 as compared to ten in 2018. All the clinical trial applications received were processed and authorised within the 90 day timeline. Among the 12 applications received for clinical trials two were phase 1 clinical trials, three phase 2, five were phase 3 and two were phase 4 as shown by the graph overleaf.



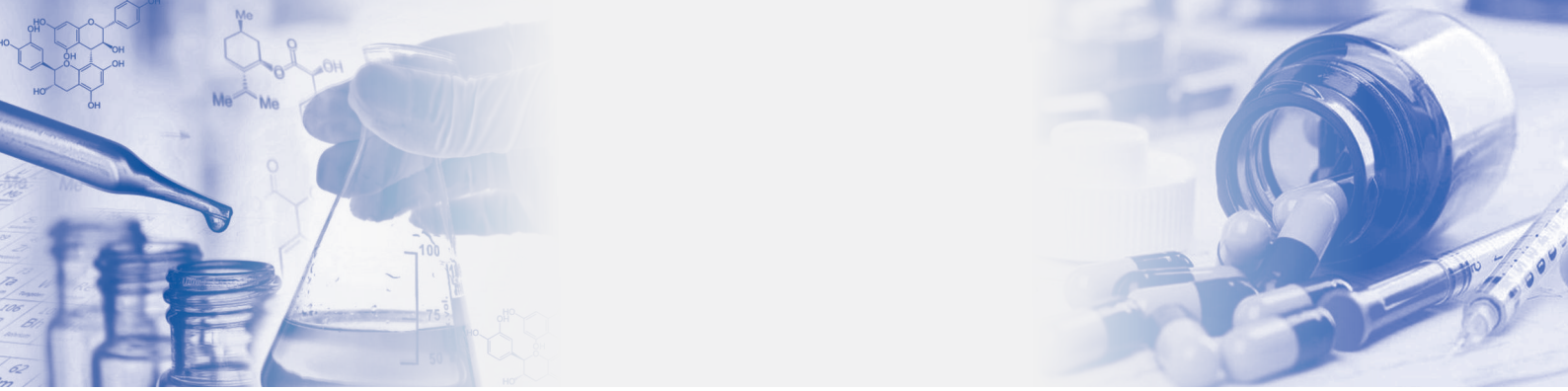


The table below classify the clinical trials applications received according to the research area.

Research Area	Number of Clinical Trials Received
HIV Prophylaxis and Treatment	6
Tuberculosis	2
Pain Management	1
Depression	1
Malnutrition	1
Tropical Diseases	1

As shown above the highest number of clinical trial applications received were for HIV prophylaxis and treatment.

Compliance with GCP is also monitored through processing of SAEs, amendments to clinical trial protocols, clarification memos, protocol deviation reports, progress reports and review of data safety monitoring board reports. The following table shows various clinical trial reports which were received and processed in 2019.



Type of report	Number of Reports Received	Number of reports
Clarification Memos	7	7
Safety reports/memos	66	66
Annual Report from	10	10
Progress reports	4	4
Protocol deviation reports	92	92
Data and Safety Monitoring Board Review reports	19	19
Section 75 Application for importation of study medicines	99	99

Chemistry Laboratory

The Medicines Control Authority Chemistry Laboratory is a National Heath Quality Laboratory whose mandate is to conduct chemical testing of medicines, which are manufactured in Zimbabwe as well as products that are imported and consumed by the Zimbabwean population. The purpose of testing is to check for quality, and safety so that the public is not exposed to substandard and falsified medical products. The areas of regulatory involvement in the National Quality Control

Programme are as indicated below:

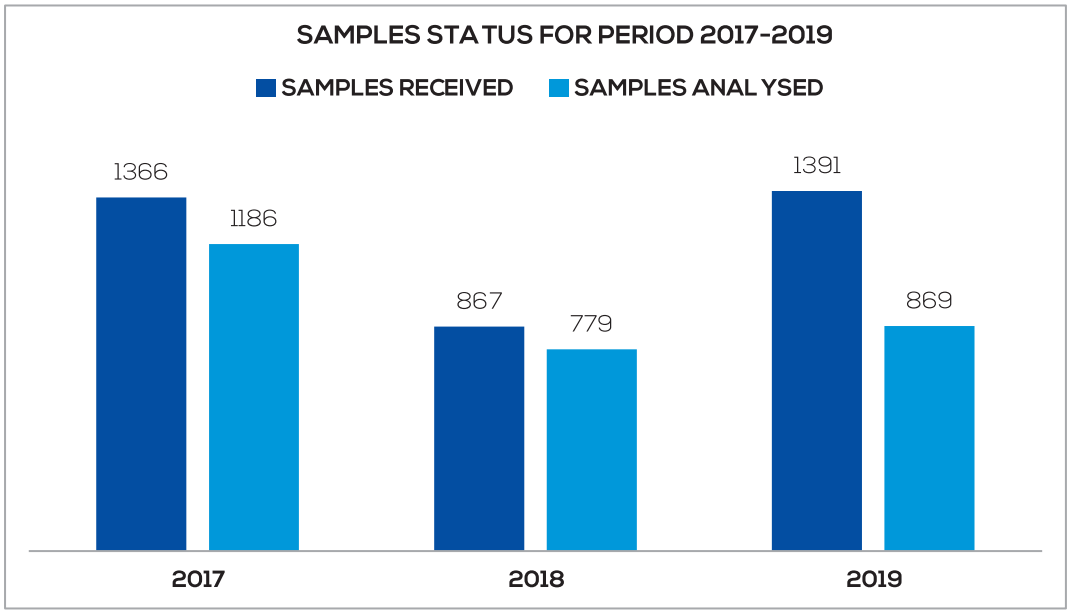
i. Pre-distribution Analysis of medicines to ensure that quality and safe products are circulated in the medicines distribution chain down to the peripheries.
ii. Post market surveillance in search of falsified and sub-standard medicines. Incompetent manufacturers are also identified in the process.
iii. Adverse event monitoring in collaboration with the Pharmacovigilance Team to confirm products defects on the market.
iv. Where pre- registration testing is necessary the laboratory performs chemical testing to establish quality of the medicines before they are allowed onto the market of Zimbabwe.

The main objective is to protect human and animal health from poor quality medicines which may increase the risk of anti-microbial resistance.

2019 activities are reflected in the statistical presentation below.

Laboratory Statistics

Figure 1.0: Trend Analaysis of Samples received and analysed by the Chemistry Laboratory (2017-2019)

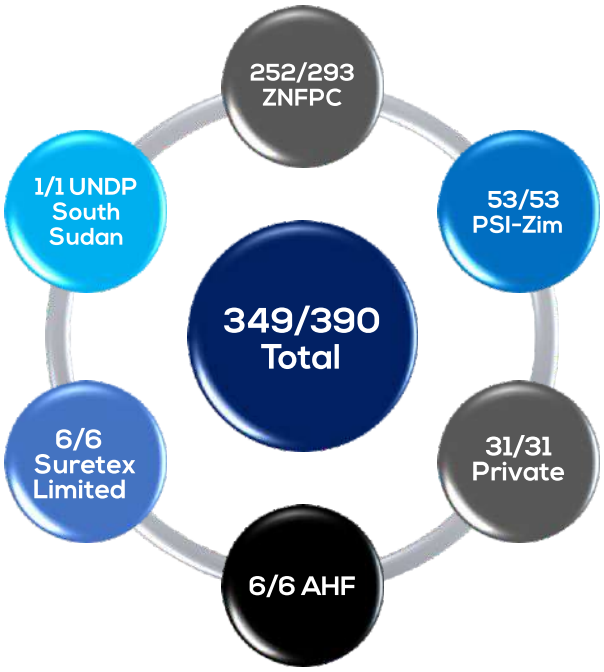


The MCAZ acknowledged the roles played by development partners such as Global Fund, UNDP and UNICEF for supporting the Authority to continue monitoring the quality and safety of the medicines on the market. It is important to follow up registered medicines in the distribution chain in order to combat the problem of counterfeits and substandard medicines.

Medical Devices Laboratory

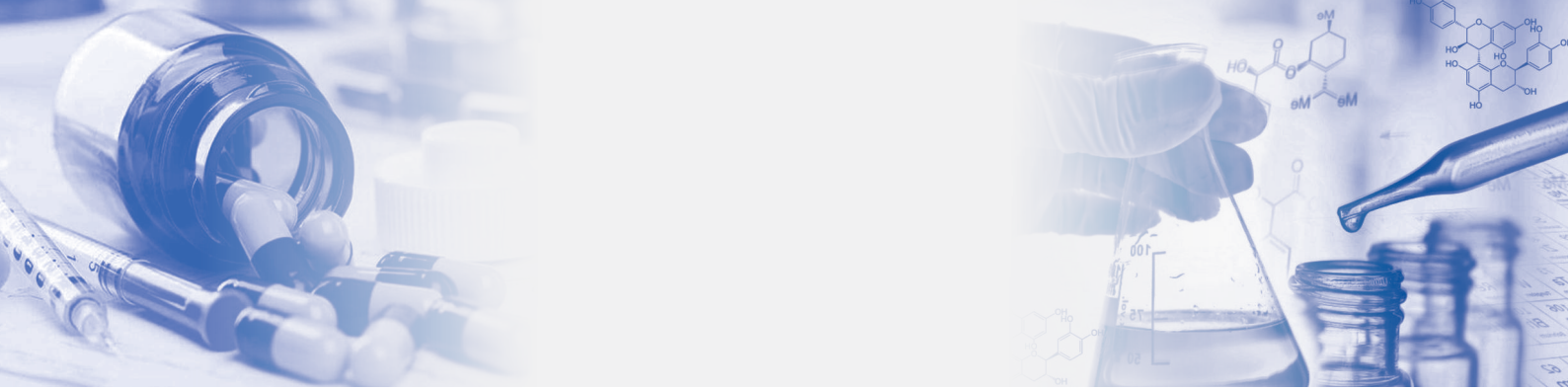
The Medical Devices laboratory does quality conformity assessment of condoms and gloves as guided by MCAZ regulations and international standard requirements. The laboratory is ISO/IEC 17025 accredited for condom testing.

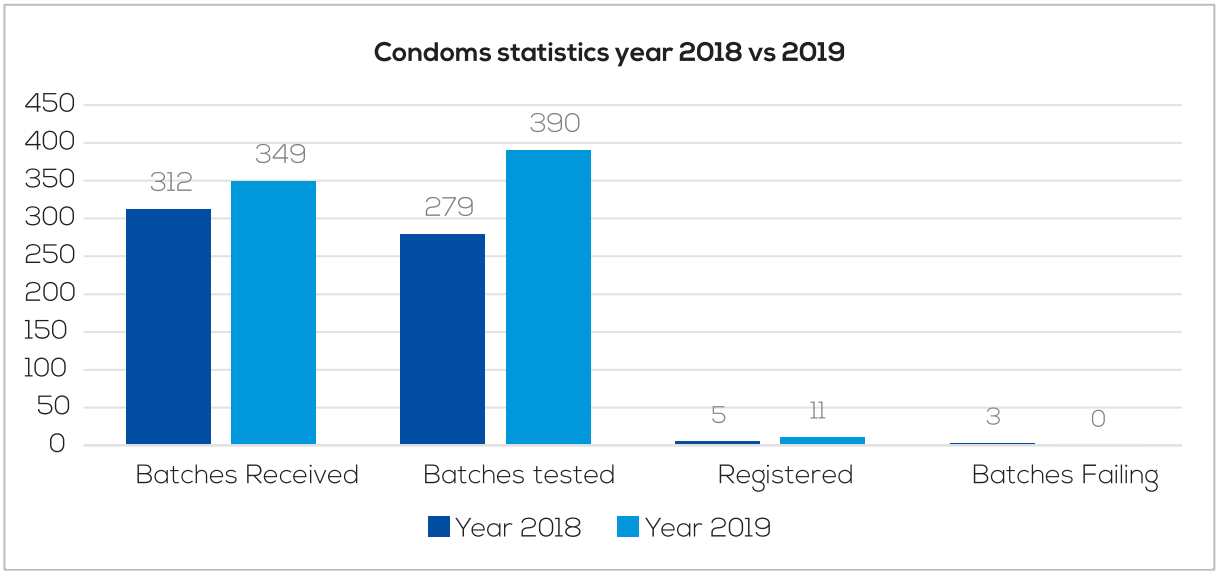
Condoms

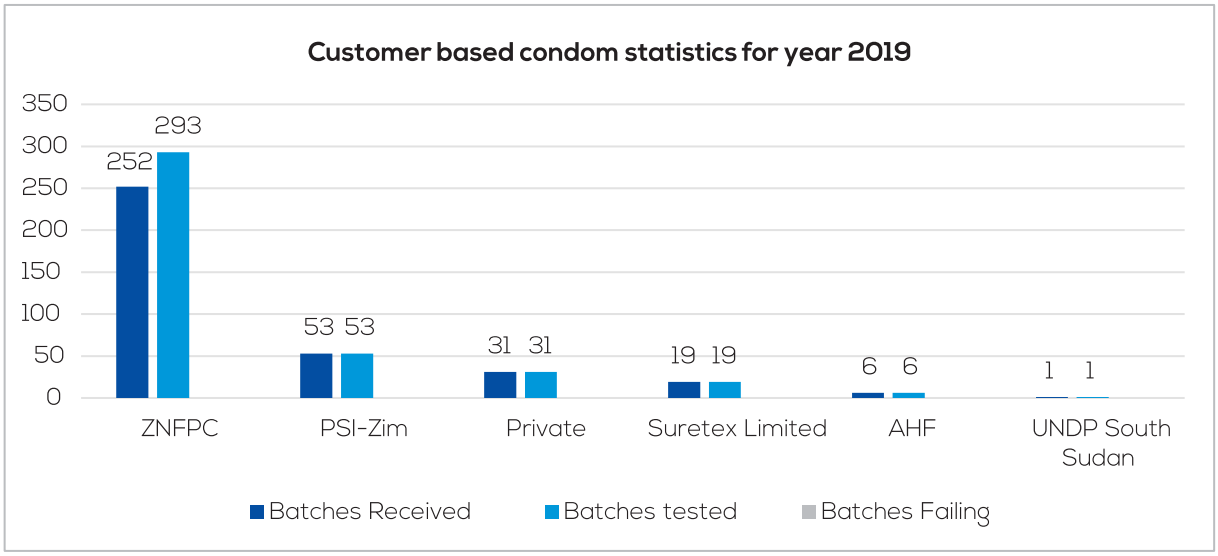


Snapshot of batches received/batches tested in 2019 according to source.

- The laboratory received three hundred and forty-nine (349) condom batches for testing in year 2019, and managed to test three hundred and ninety (390) batches. Forty-one (41) batches were carried over from year 2018 to year 2019. There was a 11.9% increase in the number of samples received from year 2018 to 2019.
- The laboratory received eleven (11) new condom registration applications, and they were all granted market authorisation.
- All batches of condoms passed quality conformity assessment tests for the period.
- SADCAS conducted a surveillance audit in February and March 2019, and the laboratory maintained its accreditation.
- The laboratory continues to participate in annual proficiency testing schemes coordinated by the FHI360 (USA) and Enersol of Australia.

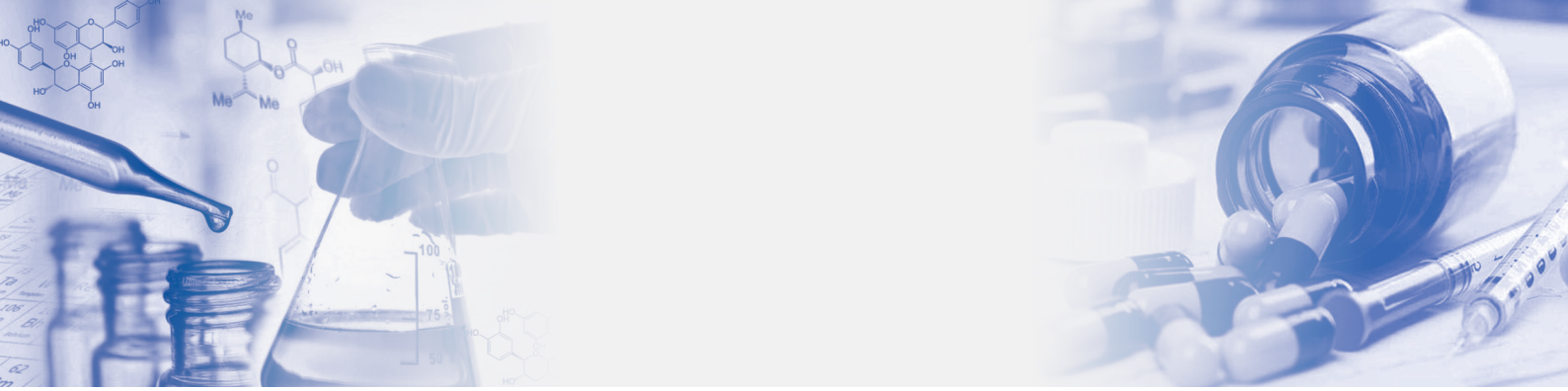


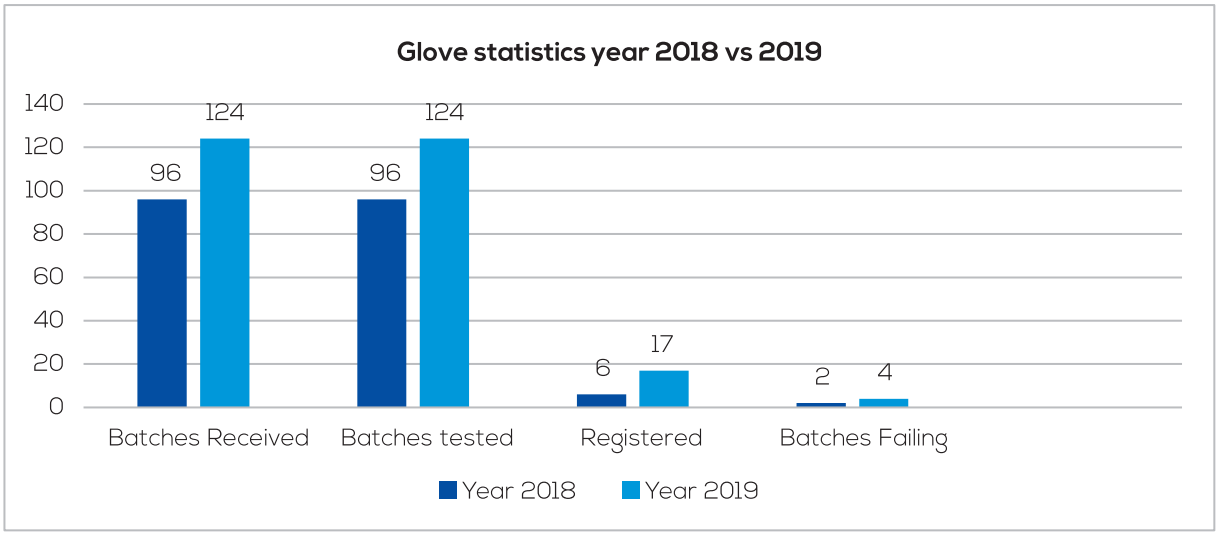




Gloves

- The laboratory received and tested one hundred and twenty-four (124) batches of gloves in year 2019.
- There was a 29.2% increase in the number of glove batches received from year 2018 to 2019.
- The laboratory received seventeen (17) new glove registration applications, and they were all granted market authorisation.
- Four (4) batches of gloves failed quality conformity assessment tests for the period.
- The laboratory continues to participate in annual proficiency testing schemes coordinated by Enersol of Australia.




Glove statistics year 2018 vs 2019
140
120
100
80
60
40
20
0
96
124
96
124
6
17
2
4
Batches Received
Batches tested
Registered
Batches Failing
Year 2018
Year 2019

Microbiology Laboratory

106 Baines Avenue Microbiology laboratory remodeling status report.

The Authority`s Microbiology laboratory is undergoing a major refurbishment project to meet WHO Standards for Pre-qualification. The project is funded by the Global Fund and implementation is being done by UNDP. The refurbishment project commenced in August, 2017 comprising two (2) sections under the project scope, as follows:

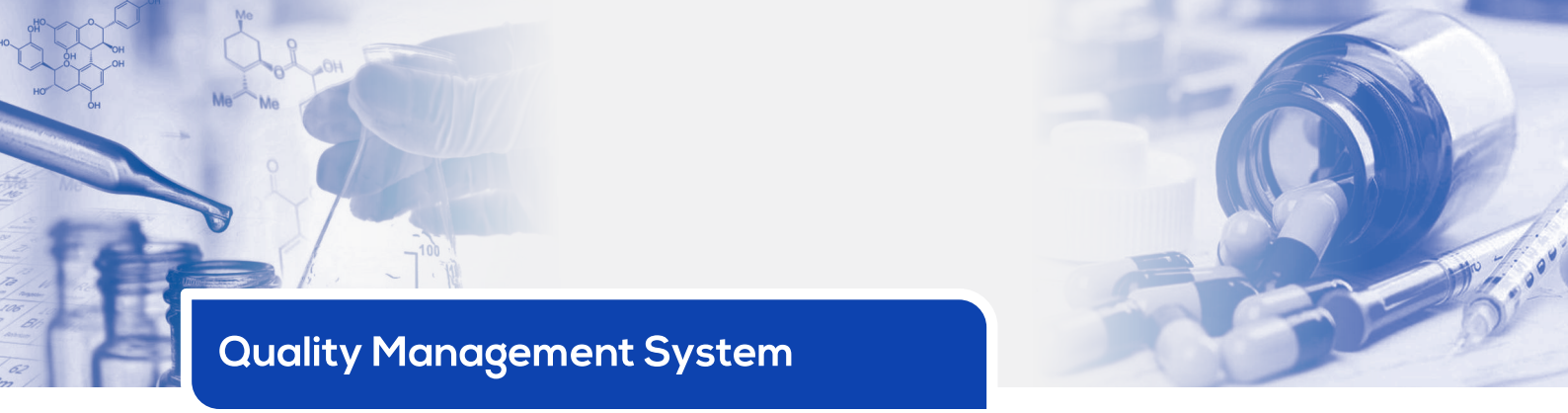
i) The main laboratory works primarily focusing on the refurbishment of the main laboratory civil works and fittings and;

ii) The Clean Room which is a specialized project where the Sterility Tests will be performed in a controlled environment

The contractors for the main works and civil works are working with a target to complete the project by the end of April, 2020. The WHO Consultant is expected to perform a site assessment of the works soon after completion to check on the facility`s conformity to WHO Standards so that the contractors could be cleared for a project close-out and formal handover of the facility to MCAZ.

Samples analysis status report

The laboratory brought forward twelve samples (12) from 2018 and received one hundred and eleven (111) samples for testing in 2019, to give a total of one hundred and twenty three (123) samples for testing in 2019. The laboratory analyzed a total of one hundred and twelve (112) samples, one (1) sample, a complementary medicine failed bio burden test. A total of eleven (11) samples were carried forward into 2020. This was due to a sharp increase in volume of samples submitted to the laboratory by one of its customers, Licensing and Enforcement Division towards end of 2019. There was a ninety five percent (95%) increase in the number of samples received by the laboratory from 2018 to 2019. This was because the laboratory was operational from the beginning of the year unlike in 2018, when the laboratory resumed operations in May.



Quality Management System

The Quality Unit has oversight of all Quality Management Systems implemented at MCAZ. This include:

- ISO 17025:2017
- ISO 9001:2015
- ISO 17020:2012
- WHO Prequalification guidelines

SADCAS Accreditation

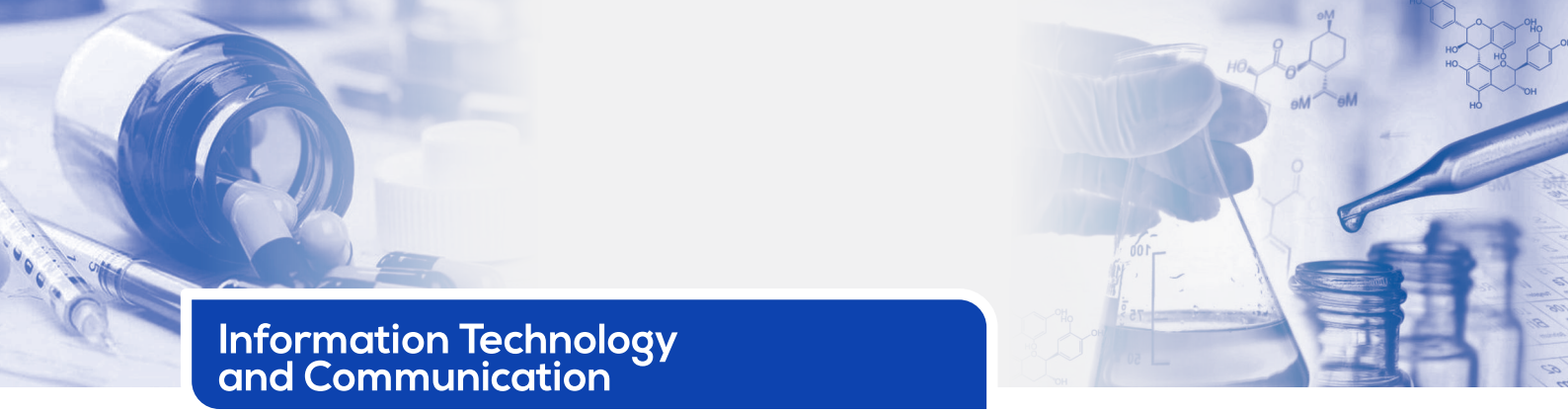
SADCAS conducted a surveillance audit for ISO 17025 in February 2019 and the laboratories were recommended for continued accreditation. In addition to this accreditation, an application for accreditation for ISO 17020 was submitted and accepted.

ISO 9001: 2015 Certification

The MCAZ received its certification to the ISO 9001:2015 standard. This certification is recognition of the organization's ability to demonstrate that it successfully implements a business and quality management system that meets the requirements of the standard.

The ISO 9001:2015 standard is designed to help organizations meet and exceed their customer's requirements and expectations. This is the essence of MCAZ's values which are customer-focus, integrity, accountability and continuous improvement. The Authority identified its internal and external issues, risks, opportunities and interested parties enabling it to set in place the measures necessary to ensure the opportunities are explored and the risks mitigated.

The certification supports the Authority to maintain the highest levels of service quality that today's business environment demands. Our customers and stakeholders now have complete assurance that MCAZ will deliver products and services that meet their requirements, while it continually strives to maintain and improve these standards that set us apart. Determining how to efficiently meet and exceed our customer's expectations is an ongoing employee owned organisation-wide effort.



Information Technology and Communication

In order to ensure effective execution of its mandate, the Authority has embarked on developing and strengthening its Information and Communication Technology (ICT) infrastructure. Automation of key processes has helped improve efficiency, providing convenience to our valued customers. Some of the key ICT projects are listed below:

ICT Projects

ZIMDIS

The Zimbabwe Drug Information System (ZIMDIS) is a web based system that replaced the old desktop application used to register all medicines in Zimbabwe. The desktop application called FoxPro had challenges of being disintegrated. Thus duplicate information existed which resulted in many inconsistencies. ZIMDIS eliminated that by integrating the Registration of Medicines, Premises and distributors of Medicines

Import/Export of Registered Medicines

This system is used to regulate the importation and exportation of registered medicines. Medicine distributors such as pharmacies can create accounts on the system for them to be able to import or export medicines. The system improves efficiency of processing applications to import/export medicines and to keep the applicant informed about his application at different stages of the process

Importation of Section 75 Medicine

Medicines not registered in ZIMDIS can still be imported and regulated in Zimbabwe. That is the purpose of the Section 75 system. It is a web-based application that processes the applications by medicine distributors to import Section 75 medicines.

e-CTR Electronic-Clinical Trial Registry System

(e-CTR System) is for processing applications for those who want to apply for clinical trials in Zimbabwe. At all stages of the process, the applicant is also notified of the progress, such as when the application has been sent to the PVCT Committee for review. After a clinical trial is approved, the non-confidential information about that clinical trial will be published for public use

e-ADR - Electronic-Adverse Drug Reaction System

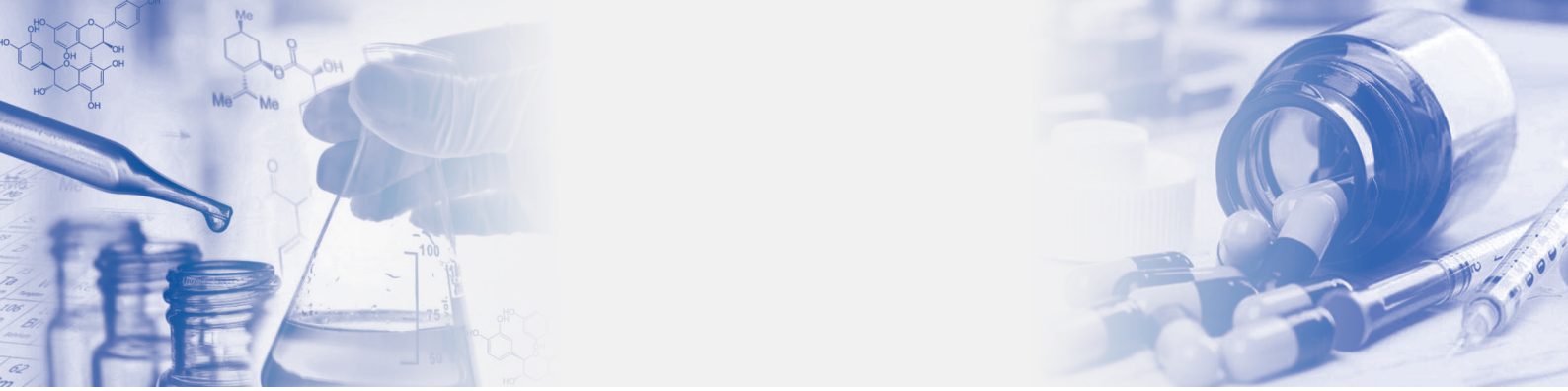
This is a pharmacovigilance system. It accessible on web, mobile and as a desktop application (both macOS and Windows). It is used for monitoring ADRs in Zimbabwe and evaluating them. It improves the effectiveness and efficiency of monitoring of such cases in Zimbabwe

e-Agenda

The Electronic Agenda system is used for distributing agendas and minutes for committee meetings. All divisions at MCAZ use this for their committee meetings so that committee members and staff members can have the required documents for committee meetings. It has significantly cut down on stationery costs for The Authority

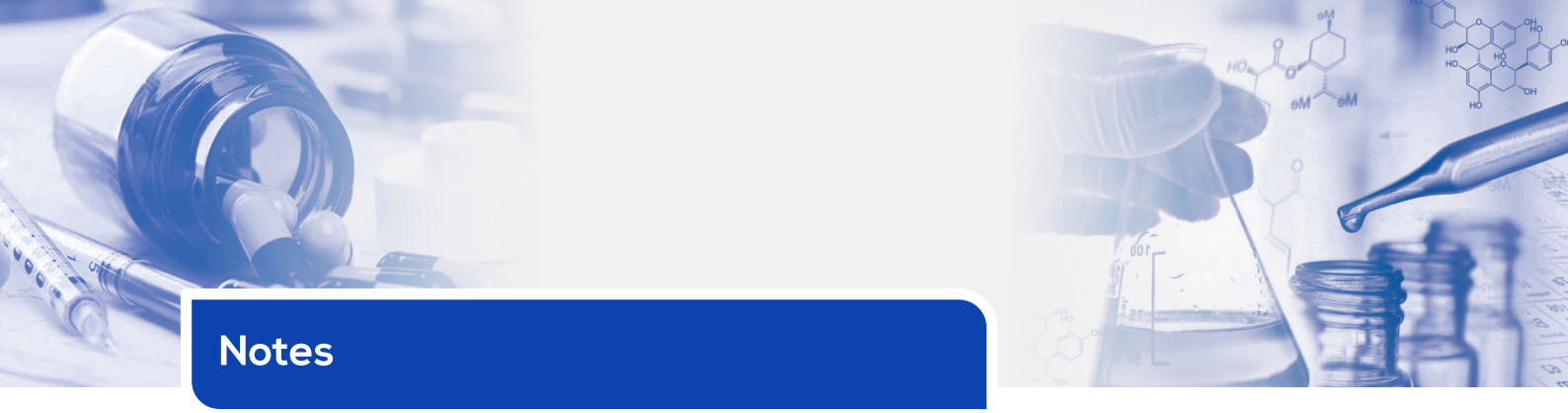
Online Drug Register

It is used for publishing to the public all registered medicines as soon as they are updated on ZIMDIS. This is a real-time processing system



Employee Self Service (ESS)
This is used by MCAZ staff to process their human resources related information and issues. These include viewing of payslips, applying for overtime, leave requests, and updating their personal information such as residential addresses

Sage ERP
The Sage ERP system was introduced to meet all ERP issues of The Authority. It helps in processing of requisitions, budgeting, producing financial statements and other financial activities for The Authority



Notes

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