ANNUAL REPORT 2018

MCAZ Medicines Control Authority of Zimbabwe


MCAZ
Medicines Control
Authority of Zimbabwe

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CONTACTS

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MCAZ Medicines Control Authority of Zimbabwe

ABBREVIATIONS

ADR	Adverse Drug Reaction
AEFI	Adverse Event Following Immunisation
AHF	Aids Healthcare Foundation
AiBST	African Institute of Biomedical Science and Technology
AMR	Antimicrobial Resistance
AMRH	African Medicines Regulatory Harmonisation
AVAREF	African Vaccine Regulatory Forum
cGPPCL	compliance with Good Practices of Pharmaceutical National Quality Control Laboratories
CGF	Corporate Governance Framework
CTD	Common Technical Document
ERM	Enterprise Risk Management
EVR	Evaluations and Registration
FHI	Family Health International
GACVS	Global Advisory Committee of Vaccine Safety
GCP	Good Clinical Practice
GF	Global Fund
GSVI	Global Vaccine Safety Initiative
HITBL	HIV Integrated Training Blended Learning
HIV	Human Immunodeficiency Virus
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IFRS	International FInancial Reporting Standards
LDP	Leadership Development Programme
LED	Licensing and Enforcement Division
MASCA	Medicines and Allied Substances Control Act
MCAZ	Medicines Control Authority of Zimbabwe
MedDRA	Medical Dictionary for Regulatory Activities
MOHCC	Ministry of Health and Child Care
NEPAD	New Partnership for Africa's Development
PECOGO	Public Entities Corporate Governance Act
PFMA	Public Finance Management Act
PSI-ZIm	Population Services International - Zimbabwe
PVCT	Pharmacovigilance and Clinical Trials
SADC	Southern African Development Community
SADCAS	Southern African Development Community Accreditation Service
TSR	Targeted Spontaneous Reporting
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
USD	United States Dollar
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organisation
ZIMCODE	National Code on Corporate Governance for Zimbabwe
ZIMRA	Zimbabwe Revenue Authority
ZNFPC	Zimbabwe National Family Planning Council

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

MESSAGE FROM THE CHAIRMAN

Dr. M Chiware

Dear shareholders:

A warm welcome to the 2018 Medicines Control Authority of Zimbabwe (MCAZ) Annual Report. This report is the fifth (5th) annual report and the review of the five-year strategic plan that commenced 1st January 2014 and ended 31st December 2018.

Overall Performance for the year 2018 and the 5 year period 2014-2018

I am glad to report that Authority managed to meet the key targets for the 2018 calendar year and the five strategy period 2014-2018, thanks to the successful achievement of key milestones in prior years leading to 2018, inspite of unstable economic environment.

Consitution of the Board

My sincere appreciation goes out to my predecessor Mrs Josephine Ncube who ably chaired the Board through the first four years of the Authority's five (5) year strategic plan. Her astute leadership contributed to succesful achievement of the Authority's 5-year Strategic Goals.

In 2018 we had a fully constituted Board which was comprised of a majority of new members appointed by the Minister of Health and Child Care (MOHCC) to fill vacancies left by out-going members who had completed their two, five-year Board tenures. Smooth continuation was facilitated by organisational systems, the experience of existing members of the Board, the competence of new members and service of the Management Team.

Authority Meetings

The Board held all its scheduled quarterly Board meetings. We had a quorum for all the four Board Meetings. We did not record any conflicts of interest for any of the Board members at any of four Board Meetings. The Board ratified and adopted the decisions that had made by its technical adviosory committees.

Board Meetings

We held all the scheduled quarterly Board Meetings where we ratified the decisions of various technical committees. Our Strategy Committee held scheduled meetings to monitor progress in implementation of the 2017 workplan and attainment of the set key milestones.

Strategy Committee

The Strategy Committee of the Board met four times in 2018 first to adopt 2018 Annual Work Plan and second to monitor its implementation every quarter. There were no major deviations in attainment of interim milestones and achievement of final targets.

The Future

The Authority is finalising the necessary legal instruments for control of medical devices, in vitro diagnostics, blood and blood products.

We will continue the work-sharing initiatives with SADC Countries in the ZAZIBONA Programme. We remain committed to support transformation of African Medicines Regulatory Harmonisation Initiative into the African Medicines Agency (AMA). We will maintain existing, and seek out new productive, partnership with other regulators on the content and abroad.

I thank our Line Ministry, my Board, Management, Staff, development partners, other local and international key stakeholders for supporting the Authority's performance, in spite of the difficulties of enforcing standards in a turbulent economic environment.

DR M CHIWARE

Chairman of the Board

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

MESSAGE FROM THE DIRECTOR GENERAL

Ms. Gugu N. Mahlangu

I have the pleasure of presenting the 2018 Annual Report to you. The year was very important to us in two ways. First, it was the final year of our five strategic plan 2014-2018 and secondly it marked the final point for review of the cumulative achievements over the entire period

Sustainable Resource Base

Our target revenue collection for 2018 was USD 4.5 million which marked a 10% growth from 2017 target of USD 4.1 million. We are glad to report that we managed to achieve the 10% growth and collected USD 4.5 which was in line with the final year target for 2018, the five year of five year strategy period 2014-2018. Achieving those targets ensured that the Authority to fund its operations through user fees.

Effective Automated Systems

The HR Unit and ICT Unit maintained the Employee Self Services for leave application, overtime claims, and viewing payslips, which was piloted in 2017. The prototype for electronic reporting of adverse drug reactions (e-ADR) developed in 2017 was perfected in 2018 thanks to the fruitful stakeholder presentation and constructive feedback. Our appreciation goes to the Global Fund and UNDP who supported development of the e-ADR system and the electronic Clinical Trials register by IntelliSOFT Consulting Ltd Kenya.

Effective Regulatory Systems

The Evaluations and Registration Division's median time to registration for 2018 was 16.25 months versus a target of 16 months. This was 2.25 months increase in median timeline from the 14 months achieved in 2017. The higher median time in 2018 may be explained by the increase in volume of applications received, evaluated and registered in 2018 relative to 2017. Our efforts to close old applications continued in 2018. Applicants who submitted satisfactory additional data had their medicines registered. Those that failed to respond in time or whose responses were inadequate to address safety, quality and efficacy issues had their products refused registration. Our Licensing and Enforcement Division continued to carry out enforcement activities to enforce adherence to standards by licensed persons operating in licensed premises. In the interest of public safety joint enforcement activities between MCAZ and the Zimbabwe Republic Police Criminal Investigations Department continued to ensure unlicensed persons operating from unlicensed facilities were brought to book.

Skilled and Competent People

We managed to retain 95% of staff members from first quarter to third quarter. However, staff attrition in the fourth quarter had exceeded the permissible 5%. This increase in staff attrition above the 5% threshold tallied with the increasing fragility of the economy and better opportunities opening up in neighbouring countries and better packages offered by other non-state institutions in Zimbabwe. A salary survey conducted by an external HR Consultancy showed that our salaries fell at the 25 percentile of the market salaries amongst institutions that employ similar cadres like the Authority. Management and the HR Committee were seized with efforts to improve MCAZ salaries from the 25th percentile to the 50th percentile also known as the median. In spite of our spirited efforts this target could not be achieved in view of the fragility of our economy, the rapid increase in cost of living in the last quarter, and a growing sense of uncertainty in the performance of revenue lines for the remainder of the year.

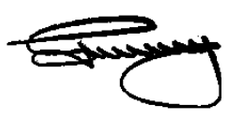
We rolled out a leadership development programme (LDP) to address managerial issues identified by our staff satisfaction survey and the subsequent 360 degree assessment of Heads of Divisions and Managers of business units. The LDP encompassed onsite lectures and discussions facilitated certified external facilitators to discuss: management, leadership, communication, stakeholder engagement, innovation, among others. In addition, the Authority availed certified external mentors for one-on-one mentorship to strength areas picked by the 360 assessment and reinforce areas that are of critical importance to manager's current roles.

Value for Money Services

One of the Authority's four values is 'Customer focus'. We maintained our customer engagement throughout the year using our scheduled Human Medicines Liaison Meetings and Veterinary Medicines Liaison Meetings. We continued to get useful feed-back and intelligence that empowered us to make appropriate policies, guidelines and informed decisions. We also had ad hoc meetings with the Palliative Care Nurses who brought to our attention the plight of patients in need palliative care. We began formulating policies that would see an increase in access to palliative care products by patients in need of such medicines.

I trust the few highlights I shared with you will create curiosity for you to peruse through the rest of this annual report, your precious time permitting.

I wish to thank the Authority and Committee members, the Management Team, all staff members, the Ministry of Health and Child Care, the development partners (Global Fund, UNDP, UNICEF, GAVI, etc.), our Legal Advisers, Bankers, our Strategy Consultancy 'Team Consulting', Health Care Providers, patients, applicants, licensees and all other stakeholders for making 2018 yet another success.



GUGU N MAHLANGU

Director General

MCAZ
BOARD MEMBERS

DR. M CHIWARE

CHAIRMAN

MRS R HOVE

DR C PASI

MS J CHIDORA

DR C DURI

MR J KUNONGA

DR C S MUTISI

DR S L MUTAMBU

MRS N SAMURIWO

MS Y M ZHOU

The Board of Directors

The Board is currently comprised of 12 non-executive directors who have a diverse mixture of qualifications, skills and expertise as required by section 4 of the MASCA. This in also in line with section 4 subsection (2) of MASCA which states that at any given time the Board should consist of not less than eight and not more than twelve members as determined by the Minister in line with the same section of the Act

Insert Pic 1

Standing, from left to right: *Dr S L Mutambu, Mr J Kunonga, Dr C Duri, Ms Y M Zhou, Dr C Pasi*
Seated, from left to right: *Ms G N Mahlangu, Hon Min Dr O Moyo, Dr M Chiware, Mrs R Hove*

REPORT FROM THE AUDITOR GENERAL

REPORT OF THE AUDITOR-GENERAL TO THE MINISTER OF HEALTH AND CHILD CARE AND THE BOARD OF DIRECTORS IN RESPECT OF THE CONSOLIDATED FINANCIAL STATEMENTS OF MEDICINES CONTROL AUTHORITY OF ZIMBABWE FOR THE YEAR ENDED DECEMBER 31, 2018

Report on the Audit of the Consolidated 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 6 to 26, which comprise the consolidated statement of financial position as at December 31, 2018, 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 section of my report, the accompanying financial statements do not present fairly, in all material respects, the financial position of Medicines Control Authority of Zimbabwe as at December 31, 2018, and its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRSs).

Basis for Adverse Opinion
The Group did not comply with the provisions of IAS 21 "The Effects of Changes in Foreign Exchange Rates". The need to account for these changes emanated from the multi-tier pricing environment that was prevailing during the year, where a product or service had different prices depending on the mode of payment, whether US$, RTGS, bond notes/coins and mobile money. Premiums and discounts were experienced on the official exchange rate of 1:1 between the US$ and RTGS, Mobile Money, Bond Notes/Coins. This pricing structure resulted in transactions bearing similarities to what one would expect with transactions that are undertaken in different currencies to which IAS 21 would apply.

The Group has maintained its functional currency as the US$ and has presented the financial statements in US$ using the official foreign exchange rate of 1:1. Had the Group applied the requirements of IAS 21, many of the elements of the accompanying financial statements would have been materially impacted and therefore the departure from the requirements of IAS 21 is considered to be pervasive. The financial effects on the financial statements of this departure have not been determined. A sensitivity analysis of how different exchange rates would impact on the statement of financial position has been presented in note 17 to the financial statements. However, these amounts presented may not reflect the opening balances, in RTGS Dollars, going forward.

Adverse Opinion on the Authority's financial statements
In my opinion, the financial statements present fairly, in all material respects, the financial position of the Medicines Control Authority of Zimbabwe as at December 31, 2018, and its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRSs).

Basis for Adverse Opinion
In my opinion, because of the significance of the matters discussed in the Basis for Adverse opinion section of my report, the accompanying financial statements do not present fairly, in all material respects, the financial position of Medicines Control Authority of Zimbabwe as at December 31, 2018, and its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRSs).

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

Key Audit Matters

Key Audit Matters are those matters that, in my professional judgment, were of most significance in my audit of the consolidated financial statements of the Medicines Control Authority of Zimbabwe for the year ended December 31, 2018. These matters were addressed in the context of my audit of the consolidated financial statements as a whole, and in forming my opinion thereon, and I do not provide a separate opinion on these matters. The key audit matters noted below relate to the audit of the financial statements.

Key Audit Matter	How my audit addressed the Key Audit Matter
Valuation of trade receivables, refer to notes 8 and 3.4.1.2 in the financial statements. Management has estimated the recoverable amount of the trade receivables for the Authority to be $545 856 as at December 31, 2018 with an allowance for credit losses of $245 854. The valuations of trade receivables are dependent on certain key assumptions that require significant management judgement. As a result, the valuation of receivables was significant to my audit. The level of judgement required in calculating the probability of default increases the risk that allowances may be inappropriately disclosed.	The audit procedures that I performed to address the risk of material misstatement relating to valuation of trade receivables included: • Reviewing members' payment history to confirm adherence to the terms and conditions of membership. • Assessing of the customers' ability to meet the obligations over time. • Evaluating the assumptions used in establishing the probability of default considering the nature and suitability of any historic data used to support these assumptions. • Evaluating the reasonability of management judgements and recalculating the allowance for credit losses assumptions made in estimating the allowance for credit losses. I was satisfied that the Authority's trade receivables were fairly valued.
Revenue recognition, refer to notes 13, 14 and 3.5 in the financial statements. The Authority's revenue amounted to $4 940 587 for the year ended December 31, 2018. Revenue is predominantly derived from medicines control income and laboratory services income. Revenue recognition is highly complex given the large number of service offerings and high volumes of transactions.	My audit procedures to address the risk of material misstatement relating to revenue recognition included: • Testing the system (internal controls) surrounding revenue. • Conducting substantive analytical procedures on revenue. • Scrutinising journals related to revenue to assess the timing and fair values of revenue recorded. • Evaluating the adequacy of the disclosures regarding the trade receivables. I was satisfied that the amount recognized was fairly stated and the related disclosures in the financial statements were appropriate.
Investment property, refer to notes 5 and 3.1.4 in the financial statements. The Authority's investment property fair value increased from $1 600 000 to $1 640 000. Valuation of the investment property is highly subjective due to the use of judgments and estimates. There may be also inadequate documentation to support the assumptions that investment properties reflect the existing business circumstances and economic conditions.	The audit procedures that I performed to address the risk of material misstatement relating to valuation of investment property included: • Reviewing whether there is adequate documentation /policy to support the assumptions that investment properties reflect the existing economic conditions and existing business circumstances. • Reviewing the assumptions used for valuation of investment property carried at fair value. • Reviewing whether the basis of assumptions used comply with IFRS 13 Fair value measurement. I was satisfied that the Authority's investment property was fairly valued.

Other Information in the Annual Report

The directors are responsible for the Other Information. The Other Information comprises all the information in the Authority's 2018 annual report. The other information does not include the financial statements and my auditor's report thereon. My opinion on the Authority's financial statements does not cover the Other Information and I do not express any form of assurance conclusion thereon. In connection with my audit of the Authority'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 Authority'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 this 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 directors are responsible for the preparation and fair presentation of these consolidated 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 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's not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

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 uncertainly 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 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.

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

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

Report on Other Legal and Regulatory Requirements

In my opinion, the 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 requirements.

04.06.2019

M.CHIRI
AUDITOR GENERAL

AUDITED
FINANCIAL STATEMENTS

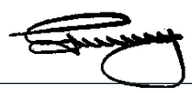
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AS AT DECEMBER 31, 2018

ASSETS	NOTE	MCAZ GROUP		AUTHORITY	
		2017	2018	2017	2018
		US$	US$	US$	US$
Non-current assets		**5 761 903**	**4 376 115**	**5 413 316**	**4 117 207**
Property, plant and equipment	4	4 121 903	2 776 115	3 554 721	2 298 612
Investment property	5	1 640 000	1 600 000	1 640 000	1 600 000
Investment in subsidiary	6	-	-	218 595	218 595
Current assets		**1 746 553**	**1 565 032**	**1 722 577**	**1 541 081**
Inventories	7	27 640	30 249	27 640	30 249
Trade and other receivables	8	633 789	846 731	621 991	835 400
Cash and cash equivalents	9	1 085 124	688 052	1 072 946	675 432
Total Assets		**7 508 456**	**5 941 147**	**7 135 893**	**5 658 288**
RESERVES AND LIABILITIES					
Reserves		**5 872 806**	**4 500 346**	**5 500 083**	**4 225 583**
Capital reserve		5 234 444	5 234 444	5 444 017	5 444 017
Accumulated fund		(1 050 599)	(932 487)	(1 341 242)	(1 218 434)
Revaluation reserve		1 450 408	-	1 397 308	-
Non controlling interest		238 553	198 389	-	-
Non-current liabilities		**388 603**	**477 309**	**384 877**	**467 551**
Deferred income	10	382 312	464 986	382 312	464 986
Deferred tax	11	3 726	9 758	-	-
Staff vehicle contribution scheme		2 565	2 565	2 565	2 565
Current liabilities		**1 247 047**	**963 492**	**1 250 933**	**965 154**
Trade and other payables	12	1 065 679	772 352	1 069 565	774 014
Leave pay provision		181 368	191 140	181 368	191 140
Total reserves and liabilities		**7 508 456**	**5 941 147**	**7 135 893**	**5 658 288**

E. Kulube
Head, Finance and Business Support



G. N. Mahlangu
Director General

M. Chiware
Authority Chairperson

AUDITED
FINANCIAL STATEMENTS

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

AS AT DECEMBER 31, 2018

	NOTE	MCAZ GROUP		AUTHORITY	
		2018	2017	2018	2017
		US$	US$	US$	US$
INCOME		**4 940 587**	**4 925 093**	**4 944 157**	**4 926 081**
Medicines control income	13	3 727 214	3 362 134	3 727 214	3 362 134
Laboratory services	14	768 390	645 191	768 390	645 191
Other income	15	444 983	917 768	448 553	918 756
EXPENDITURE		**5 060 888**	**4 917 263**	**5 075 179**	**4 926 909**
Employments costs	16	3 146 630	2 917 505	3 146 630	2 917 505
Administration costs	18	1 914 258	1 999 758	1 928 549	2 009 404
(Deficit)/Surplus for the year		**(120 301)**	**7 830**	**(131 022)**	**(828)**
Taxation	**11**	**(2 761)**	**(2 230)**	**-**	**-**
Total comprehensive (loss)/ income		**(123 062)**	**5 600**	**(131 022)**	**(828)**
Profit attributable to:		**1 247 047**	**963 492**	**1 250 933**	**965 154**
Equity holders of the parent company		(126 326)	2 964	1 069 565	774 014
Non controlling interest		3 264	2 636	181 368	191 140
(Deficit)/surplus for the year		**(123 062)**	**5 600**	**(131 022)**	**(828)**

AUDITED
FINANCIAL STATEMENTS

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

STATEMENT OF CHANGES IN RESERVES

AS AT DECEMBER 31, 2018

GROUP	Accumulated Fund	Capital Reserve	Revaluation Reserve	Total Reserves	Non-controlling Interest	Total Reserve
	US$	US$	US$	US$	US$	US$
Balance as at January 1, 2017	**(935 451)**	**5 234 444**	**-**	**4 298 993**	**195 753**	**4 494 746**
Deficit for the year	2 964	-	-	2 964	2 636	5 600
Balances as at December 31, 2017	**(932 487)**	**5 234 444**	**-**	**4 301 957**	**198 389**	**4 500 346**
Balances as at January 1, 2018	**(932 487)**	**5 234 444**	**-**	**4 301 957**	**198 389**	**4 500 346**
Deficit for the year	(126 326)	-	-	(126 326)	3 264	(123 062)
Revaluation of fixed assets			1 450 408	1 450 408	36 900	1 487 308
Realised gain on revalued assets	8 214			8 214		8 214
Balance as at December 31, 2018	**(1 050 599)**	**5 234 444**	**1 450 408**	**5 634 253**	**238 553**	**5 872 806**

AUTHORITY	Accumulated Fund	Capital Reserve	Revaluation Reserve	Total Reserves
	US$	US$	US$	US$
Balance as at January 1, 2017	**(1 217 606)**	**5 444 017**	**-**	**4 226 411**
Deficit for the year	(828)	-	-	(828)
Balances as at December 31, 2017	**(1 218 434)**	**5 444 017**	**-**	**4 225 583**
Balances as at January 1, 2018	**(1 218 434)**	**5 444 017**	**-**	**4 225 583**
Deficit for the year	(131 022)	-	-	(131 022)
Revaluation of fixed assets		-	1 397 308	1 397 308
Realised gain on revalued assets	8 214	-	-	8 214
Balance as at December 31, 2018	**(1 341 242)**	**5 444 017**	**1 397 308**	**5 500 083**

AUDITED
FINANCIAL STATEMENTS

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

CONSOLIDATED STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED DECEMBER 31, 2018

	NOTE	MCAZ GROUP		AUTHORITY	
		2018	2017	2018	2017
		US$	US$	US$	US$
Net cash flow from operating activities		**569 555**	**67 510**	**557 120**	**62 138**
(Deficit) / surplus for the year		(120 301)	7 830	(131 022)	(828)
Adjusted for non cash items:		**181 509**	**(5 066)**	**176 573**	**(15 442)**
Depreciation	4	333 148	383 247	328 182	370 747
Taxation		-	(2 112)	-	-
(Decrease) / increase in provision for leave pay		(9 772)	1 628	(9 772)	1 628
Fair value adjustment on investment property		(40 000)	(250 541)	(40 000)	(250 541)
Deferred income	10	(82 674)	(108 774)	(82 674)	(108 774)
Profit on disposal of property, plant and equipment		(15 159)	(10 907)	(15 159)	(10 907)
Interest earned		(4 034)	(17 607)	(4 004)	(17 595)
Working capital changes:		**508 347**	**64 746**	**511 569**	**78 408**
Decrease / (increase) in inventory		2 609	(7 007)	2 609	(7 007)
Increase in trade and other receivables		212 942	(117 166)	213 409	(105 284)
Increase in trade and other payables		292 796	188 919	295 551	190 699
Taxation		**(8 262)**			
Net cash flow from investing activities:		**(164 221)**	**(67 953)**	**(159 606)**	**(67 545)**
Purchase of property, plant and equipment		(191 726)	(85 634)	(187 081)	(85 214)
Additions to investment property		-	(10 959)	-	(10 959)
Proceeds from disposal of property, plant and equipment		23 471	11 033	23 471	11 033
Interest received		4 034	17 607	4 004	17 595
Net Increase/(decrease) in cash and cash equivalents		**397 072**	**(443)**	**397 514**	**(5 407)**
Cash and cash equivalents at beginning of the year		688 052	688 495	675 432	680 839
Cash and cash equivalents at year end	**9**	**1 085 124**	**688 052**	**1 072 946**	**675 432**

MCAZ GROUP
Property, plant and equipment

NOTE 4.0	Freehold Land	Buildings	Plant & Machinery	Motor Vehicles	Computer & Equip-ment	Office Equipment	Furniture & Fittings	Work in progress	Total 2018	Total 2017
	US$	US$	US$	US$	US$	US$	US$	US$	US$	US$
Opening carrying amount	**947 406**	**940 557**	**593 499**	**42 181**	**78 101**	**34 133**	**90 016**	**50 222**	**2 776 115**	**3 073 854**
Gross carrying amount	947 406	1 200 787	1 890 230	519 535	362 152	114 516	195 551	50 222	5 280 399	5 435 975
Accumulated depreciation	-	(260 230)	(1 296 731)	(477 354)	(284 051)	(80 383)	(105 535)	-	(2 504 284)	(2 362 121)
Additions at cost	-	-	5 609	88 787	9 524	4 632	21 618	61 556	191 726	85 634
Revaluation	792 595	649 213	-	56 567	-	-	-	-	1 498 375	-
Disposals carrying amount	**-**	**-**	**-**	**(11 067)**	**-**	**(98)**	**-**	**-**	**(11 165)**	**(126)**
Disposals at cost	-	-	-	(96 875)	(2 567)	(2 739)	(125)	-	(102 306)	(73 345)
Accumulated depreciation on disposals	-	-	-	85 808	2 567	2 641	125	-	91 141	73 219
Depreciation for the year	-	(31 305)	(189 271)	(45 321)	(33 367)	(13 637)	(20 247)	-	(333 148)	(383 247)
Closing 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	5 448 264
Accumulated depreciation	-	(291 535)	(1 486 002)	(436 867)	(314 851)	(91 379)	(125 657)	-	(2 746 291)	(2 672 149)

AUTHORITY
Property, plant and equipment

NOTE 4.1	Freehold Land	Buildings	Plant & Machinery	Motor Vehicles	Computer & Equip-ment	Office Equipment	Furniture & Fittings	Work in progress	Total 2018	Total 2017
	US$	US$	US$	US$	US$	US$	US$	US$	US$	US$
Opening carrying amount	**592 406**	**818 474**	**593 499**	**42 181**	**78 101**	**34 133**	**90 016**	**49 802**	**2 298 612**	**2 584 271**
Gross carrying amount	592 406	1 055 787	1 890 230	519 535	362 152	114 516	195 551	49 802	4 779 979	4 935 975
Accumulated depreciation	-	(237 313)	(1 296 731)	(477 354)	(284 051)	(80 383)	(105 535)	-	(2 481 367)	(2 351 704)
Additions at cost	-	-	544	88 787	9 524	4 632	21 618	61 976	187 081	85 214
Revaluation	727 595	624 213	-	56 567	-	-	-	-	1 408 375	-
Disposals carrying amount	**-**	**-**	**-**	**(11 067)**	**-**	**(98)**	**-**	**-**	**(11 165)**	**(126)**
Disposals at cost	-	-	-	(96 875)	(2 567)	(2 739)	(125)	-	(102 306)	(73 345)
Accumulated depreciation on disposals	-	-	-	85 808	2 567	2 641	125	-	91 141	73 219
Depreciation for the year	-	(26 592)	(189 018)	(45 321)	(33 367)	(13 637)	(20 247)	-	(328 182)	(370 747)
Closing carrying amount	**1 740 001**	**1 558 465**	**409 837**	**131 147**	**54 258**	**25 030**	**91 387**	**111 778**	**3 554 721**	**2 298 612**
Gross carrying amount	1 740 001	1 850 000	1 895 839	568 014	369 109	116 409	217 044	111 778	6 273 129	4 947 844
Accumulated depreciation	-	(291 535)	(1 486 002)	(436 867)	(314 851)	(91 379)	(125 657)	-	(2 718 408)	(2 649 232)

AUDITED
FINANCIAL STATEMENTS

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2018

NOTES		MCAZ GROUP		AUTHORITY	
		2018	2017	2018	2017
		US$	US$	US$	US$
5	**Investment property**				
	Opening fair value	1 600 000	1 338 500	1 600 000	1 338 500
	Fair value adjustment	40 000	250 541	40 000	250 541
	Transfer from property, plant and equipment	-	10 959	-	10 959
	Closing value	**1 640 000**	**1 600 000**	**1 640 000**	**1 600 000**
6	**Investment in subsidiary**				
	Percentage Discount (Pvt) Ltd	-	-	218 595	218 595
7	**Inventories**				
	Fuel	3 990	9 606	3 990	9 606
	Provisions	4 947	7 740	4 947	7 740
	Stationery consumables	18 703	12 903	18 703	12 903
		27 640	**30 249**	**27 640**	**30 249**
8	**Trade and other receivables**				
	Trade receivables	791 710	908 406	779 912	897 075
	Allowance for credit losses	(245 854)	(219 438)	(245 854)	(219 438)
	Prepayments	60	8 890	60	8 890
	Rentals - Mishonga Gardens	28 708	28 708	28 708	28 708
	Staff Receivables	2 940	62 789	2 940	62 789
	Sundry receivables	56 225	57 376	56 225	57 376
		633 789	**846 731**	**621 991**	**835 400**
9	**Cash and cash equivalents**				
	Bank	1 084 808	687 747	1 072 630	675 127
	Funds on placement	316	305	316	305
		1 085 124	**688 052**	**1 072 946**	**675 432**
10	**Deferred income**				
	Opening carrying amount	464 986	573 760	464 986	573 760
	Amortisation charge for the year	(82 674)	(108 774)	(82 674)	(108 774)
		382 312	**464 986**	**382 312**	**464 986**

AUDITED
FINANCIAL STATEMENTS

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2018

NOTES		MCAZ GROUP		AUTHORITY	
		2018	2017	2018	2017
		US$	US$	US$	US$
11	**Income tax expense**				
	Major components of tax expense				
	Current tax				
	Current tax	53 779	(32 940)	-	-
	Deferred tax				
	Movement on temporary difference	(51 018)	35 170	-	-
		2 761	**2 230**	**-**	**-**
11.1	**Tax reconciliation**				
	Profit before tax	10 721	8 659	-	-
	Notional tax thereon at a rate of 25.75%	2 761	2 230	-	-
		2 761	**2 230**	**-**	**-**
11.2	**Deferred tax**				
	Analysis of temporary differences				
	Investment property				
	Investment property	3 726	9 758	-	-
	Net deffered tax liabilitiy	**3 726**	**9 758**	**-**	**-**
12	**Trade and other payables**				
	Audit fees	15 325	14 415	15 325	14 415
	Trade payables	70 363	115 733	69 270	115 300
	Sundry payables	959 921	613 425	959 921	613 425
	Related party payables	-	-	7 740	4 325
	Tax payable	2 761	2 230	-	-
	Unallocated income	17 309	26 549	17 309	26 549
		1 065 679	**772 352**	**1 069 565**	**774 014**

AUDITED
FINANCIAL STATEMENTS

NOTES		MCAZ GROUP		AUTHORITY	
		2018	2017	2018	2017
		US$	US$	US$	US$
13	**Medicines control income**				
	Amendment fees	143 050	146 911	143 050	146 911
	Clinical trials	24 100	46 200	24 100	46 200
	Dangerous drug license	-	5 625	-	5 625
	Drug registration and forensic examination	22 730	5 628	22 730	5 628
	Import and export licenses	391 751	325 018	391 751	325 018
	Inspection	416 600	359 410	416 600	359 410
	Persons and premises licenses	162 517	159 800	162 517	159 800
	Registration fees	826 492	669 625	826 492	669 625
	Renewal of licenses	417 810	393 053	417 810	393 053
	Retention fees	886 456	826 550	886 456	826 550
	Sales representatives and wholesale dealers	183 540	164 521	183 540	164 521
	Unregistered medicines	181 738	207 193	181 738	207 193
	Veterinary permits	70 430	52 600	70 430	52 600
		3 727 214	**3 362 134**	**3 727 214**	**3 362 134**
14	**Laboratory services income**				
	Condom testing	84 890	58 120	84 890	58 120
	Complementary medicines	47 400	20 808	47 400	20 808
	Glove testing	12 650	11 863	12 650	11 863
	Medical devices - registration	2 000	4 400	2 000	4 400
	Samples - external clients	621 450	550 000	621 450	550 000
		768 390	**645 191**	**768 390**	**645 191**

AUDITED
FINANCIAL STATEMENTS

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2018

NOTES		MCAZ GROUP		AUTHORITY	
		2018	2017	2018	2017
		US$	US$	US$	US$
15	**Other income**				
	Amortisation for the year	82 674	108 774	82 674	108 774
	Decrease in provision for leave pay	9 772	-	9 772	-
	Donations	111 876	145 257	111 876	145 257
	Interest earned	4 034	17 607	4 004	17 595
	Rentals	148 571	147 834	148 571	147 834
	Fair value adjustment	40 000	250 541	40 000	250 541
	Sundry income	32 897	236 848	36 497	237 848
	Profit on disposal of property, plant and equipment	15 159	10 907	15 159	10 907
		444 983	**917 768**	**448 553**	**918 756**
16	**Employment costs**				
	Salaries and wages	2 736 266	2 530 680	2 736 266	2 530 680
	Pension and medical aid	332 509	330 622	332 509	330 622
	Staff training expenses	14 416	23 057	14 416	23 057
	Staff welfare	63 439	33 146	63 439	33 146
		3 146 630	**2 917 505**	**3 146 630**	**2 917 505**
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	43 684	43 997	43 684	43 997
	Board members fees	164 050	168 345	160 375	163 850
		207 734	**212 342**	**204 059**	**207 847**
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	13 269	9 840	13 269	9 840
	Director General salary	83 529	84 995	83 529	84 995
		96 798	**94 835**	**96 798**	**94 835**

NOTES		MCAZ GROUP		AUTHORITY	
		2018	2017	2018	2017
		US$	US$	US$	US$
18	**Administration expenses**				
	Audit fees	16 500	15 915	15 000	14 415
	Board fees	207 734	212 342	204 059	207 847
	Bank charges	36 650	26 320	36 090	25 831
	Communications	53 735	48 668	53 735	48 668
	Consumables	42 487	29 865	42 487	29 865
	Credit losses	-	260	-	260
	Directors expenses	21 240	19 252	21 240	19 252
	Depreciation	333 148	383 247	328 182	370 747
	General administration	82 764	57 247	112 764	86 668
	Inspections	211 696	194 560	211 696	194 560
	IT expenses	8 635	14 768	8 635	14 768
	Legal and professional fees	60 937	90 659	56 596	90 659
	Printing and stationery	92 762	57 957	92 762	57 957
	Increase in allowance for credit losses	26 416	-	26 416	-
	Increase in provision for leave pay	-	1 628	-	1 628
	Public relations	77 753	77 384	77 753	77 384
	Quality assurance costs	17 788	84 738	17 788	84 738
	Rates, electricity and water	24 306	32 408	24 306	32 408
	Repairs and maintenance	147 595	142 007	147 595	141 717
	Security and insurance costs	41 310	30 358	40 643	29 857
	Strategic planning	124 765	165 922	124 765	165 922
	Subscriptions	10 755	11 613	10 755	11 613
	Travelling and subsistence	123 408	114 105	123 408	114 105
	Vehicle running costs	151 874	188 535	151 874	188 535
		1 914 258	**1 999 758**	**1 928 549**	**2 009 404**

REPORT ON **GOVERNANCE AND RISK**

The Board (Authority) continues to recognize that in order to effectively bring value to the Authority' strategy and business, it must observe good corporate governance, effective risk management systems and a sound control framework. The limited resources at the Authority's disposal calls upon the authority to put in place responsive governance systems for it to fulfill its national mandate.

The Board as part of its mandate continues to give importance to the principles of transparency, integrity, and accountability in accordance with the requirements set out by the Medicines and Allied Substance Control Act (MASCA) [Chapter 15.03] and other laws, regulations, standards and best practices among others:

- Public Entities Corporate Governance Act (PECOGO)
- The Public Finance Management (PFMA) Act Chapter (22.19);
- The National Code on Corporate Governance for Zimbabwe (ZIMCODE),
- The King Code on Corporate Governance 2009 (King III),
- The Corporate Governance Framework (CGF) for State Enterprises and Parastatals and
- The International Financial Reporting Standards (IFRS).

	Board and Committee Attendance (From 1 January 2018 to 31 December 2018)							
	Board		Audit Committee		Human Resources Committee		Finance Committee	
	Attended	Possible	Attended	Possible	Attended	Possible	Attended	Possible
Mrs. J. Ncube	1	6			4	4		
Dr. A. F. Zinanga	1	6					4	4
Dr. P Muvavarirwa	1	6			2	4	1	4
Mrs J. Chaibva	1	6	1	5				
Dr. P. Chonzi	1	6	1	5				
Dr. R. Gwisai	1	6			1	4		
Dr. C Pasi	4	6						
Mrs. R. Hove	5	6						
Dr. C.C. Maponga	1	6						
Mr. J Kunonga	6	6	5	5	4	4		
Dr.C.S.Mutisi	4	6						
Mrs.J.Chidora	5	6						
Mrs. D. Mandaza	6	6						
Dr. M. Chiware	5	6	1	5	1	4	3	4
Ms. Y. Zhou	1	6					1	4
Dr. C. Duri	5	6						
Dr. S. L. Mutambu	2	6						
Mrs. N. G. Maphosa			4	5				
Mr. F. Gwiza			3	5				
Mr. C. D Mahofa			4	5				
Mr. E. Jinda					3	4		
Mrs. F.Chinogurei					4	4		
Mr. I Ruzengwe							2	4
Mr. C Shoniwa							4	4
Mrs. N. Samuriwo	2	6						

Note
Only attendance for Committees that require to be established in terms of section 3.12 of the Corporate Governance Framework for State Enterprises and Parastatals have been reported on in the table.
Overall the meeting attendance rate was satisfactory and in sufficient numbers to form a quorum. This also ensured that the debates were robust enough to enable matters to be discussed with finality.

REPORT ON
GOVERNANCE AND RISK

The Management Team

The management team for 2018 is listed in the table to the right;

NAME	POSITION
Ms G.N. Mahlangu	DirectorGeneral
Dr W. Wekwete	Head, Evaluations & Registrations Division
Mr R. Rukwata	Head, Licensing and Enforcement Division
Mrs P. P. Nyambayo	Head, Pharmacovigilance and Clinical Trials Division
Mrs B. Dube	Head, Chemistry Division
Mr E. Kulube	Head, Finance and Business Support Division
Mr T. Munhenga	Head, Human Resources Unit
Mrs. A Chikowore	Quality Manager
Mr T. Gonho	Manager, Microbiology and Medical Devices Unit
Mr M. Mutizira	Internal Auditor
Mr T Nyovhi	ICT Manager
Mr I. Ganyani	Finance Manager
Mr. F. Tembo	Administration Manager
Ms C. Samatanga	Chief Regulatory Officer, LED
Ms T. Sithole	Chief Regulatory Officer, EVR
Mr C. Shamuyarira	Chief Analyst, Chemistry

The management team is accountable to the Board. To allow the Board to discharge its duties adequately, the management team and staff are required to provide periodic updates and answer any queries that the Board may have on the operations and planning of the organisation.

Enterprise Risk Management

The Board recognises and proactively manages risk. An Enterprise Risk Management (ERM) framework to identify, assess and manage risks has been in operation since 2011. The main objective of this framework is to ensure that risk management is embedded throughout the organization's processes. The Audit Committee reviews the effectiveness of the framework. Pursuant to this, consolidated risk reports are discussed at the Committee's quarterly meetings where the Committee also assesses the effectiveness of the mitigating strategies put in place. High risks are then brought to the attention of the Board in compliance with the ERM Framework. In the 2019 year, the Authority will embark on the formulation of it Business Continuity Plan Framework (BCP). The BCP framework will outline how the Authority business will continue operating during an unplanned disruption in service.

Code of Ethics and Anti-Corruption Policy

The Authority has an Anti-Corruption Policy and a Code of Ethics that were approved by the Board. The policy documents are applicable to Board and Committee Members and Authority staff members. These are avaialble on the Authority's website.

Subscription to Deloitte TIP Offs Anonymous

In line with the latest Corporate Governance trends, the Authority subscribed to Deloitte Tip – Offs Anonymous with effect from the 1st of February, 2016. The subscription allows our stakeholders to immediately and anonymously report on theft, fraud, dishonesty, corruption, harassment and conflict of interest amongst other such vices that may hamper our continued delivery of transparent and excellent service by Board, Committee members and Authority staff members.

Internal Audit

The Internal Audit function is carried out by the Internal Audit Unit based on an Internal Audit Charter that was approved by the Audit Committee.

The Internal Audit Unit provides independent, objective assurance and consulting services designed to add value and improve the MCAZ's operations. The Unit helps the organization to accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of the governance, risk management and control processes through:

- Performing annual risk assessments throughout the organization and developing an annual risk based internal audit plan and work plan.
- Performing an independent and objective assessment of the effectiveness of governance, risk management and control framework;
- Systematically analysing and evaluating business processes and associated controls;
- Providing a source of information as appropriate, regarding instances of fraud, corruption, unethical behaviour and other irregularities and
- Providing quarterly reports to the Audit Committee.

The Unit adopts a risk-based approach in formulating its audit plan and work plan. The plans are therefore informed by the organizational objectives and strategies as well as risks facing the organization. The audit plan and work plans are approved by the Audit Committee annually.

REPORT ON
HUMAN CAPITAL

HUMAN RESOURCES COMMITTEE

The Authority values the contribution made by its employees. It strives to ensure that best labour practices that uphold the rights of employees are followed. The Human Resources Committee that was established in 2011 continues to review and oversee the formulation and implementation of the recruitment, remuneration and retention policies of the Authority. The Committee also ensures that the appropriate organizational structure is in place to achieve the Authority's goals.

MR TENDAYI MUNHENGA

Head, Human Resources

Every effort is made to maintain high staff retention rates and keep attrition rates to below the permissible 5% threshold. However, this year witnessed attrition rates exceeding this threshold, especially towards the end of the year, owing to better employment opportunities and more favorable packages being offered.

EFFORTS TO IMPROVE STAFF WELFARE

The Authority continued with the implementation and review of some of its Human Resources policies to ensure high employee welfare, empowerment and satisfaction. The policies include:

- Recruitment
- Benefits and Schemes
- Alignment of salaries to market trends, from 25th percentile to 50th percentile

2018 STAFF COMPLEMENT

Total	115
Female	55
Male	60

INSERT PICTURE 2

From left to right:

Dr M Chiware (Chairperson, MCAZ Board), Dr William Wekwete (Head, Evaluations and Registration), Ms Gugu N. Mahlangu (Director General, MCAZ)

Dr William Wekwete was one of the recipients of a Long Service Award, following 20 years of service to MCAZ.

In an effort to recognize the immense work that staff put in to ensure the MCAZ mandate is executed effectively, through the Human Resources Division, staff receive Long Service Awards following 5 years, 10 years, 15 years, 20 years, 25+ years of continuous service to the Authority. Such recognition is critical for improving staff motivation.

REPORT ON
HUMAN ALLOPATHIC MEDICINES

DR WILLIAM WEKWETE
Head, Evaluations & Registration

The Human Allopathic Medicines Unit continues to ensure that human allopathic products intended for marketing in Zimbabwe comply with MASCA [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.

305
Applications for registration of Human Allopathic Medicines

249
Registered

34
Refused Registration

4
Withdrawn

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 previous years and those received in the reporting year.

Medicines approved by MCAZ following rigorous review and evaluation.

Participants from Zambia, Zimbabwe, Botswana, Namibia, South Africa, Malawi attending one of the 4 annual sessions of the ZAZIBONA collaborative registration process.

The overall median timeline to registration in 2018 was 488 days (16.25 months). This is inclusive of the manufacturers' time to respond to queries.

The register of approved human medicines is available on the MCAZ website and is updated on a quarterly basis. The MCAZ assessors continue to receive exposure to WHO Prequalification training and active participation in dossier review.

The MCAZ continued to participate in the 4 annual sessions of ZAZIBONA collaborative registration process. A total of 44 new products were received, Zimbabwe was the lead assessor for 10 applications. In 2017 the final outcomes were 14 approvals and 10 rejections Through the Zazibona collaboration, the MCAZ was involved in the drafting of harmonised guidelines for product information within the SADC region.

As a Centre of Regulatory Excellence designated by the African Medicines Regulatory Harmonisation (AMRH) of NEPAD Agency of the AU, the Evaluations Division provides hands-on training on Quality and Bioequivalence dossier evaluation in October every year.

The MCAZ also hosted a training on assessment of Biosimilar therapeutic products. The training was attended by regulators from the MCAZ as well as assessors from National Medicine Regulatory Authorities from the following countries; Zambia, Botswana and Namibia. This training was conducted by an expert from the Australia Therapeutic Goods Administration (TGA), Dr Kevin Grant.

The MCAZ received funding from the European and Developing Countries Clinical Trials (EDCTP) to offer training to regulators and Industry in the region. This grant will run for three years.

The Division continued to actively participate in the One Health Antimicrobial Resistance (AMR) Core Group and Technical Working Groups, in the fight against antimicrobial resistance.

Summary of product registration

For the past years there has been a general steady increase in numbers of applications received with an average of 270 applications per year (range 225-305)

The numbers of new applications evaluated every year has been fluctuating from 261 to 321 with a mean of 288

The numbers of applications registered every year has been increasing from 150 to 249 with a mean of 190 per year. Some literature shows that registration of medicines does not automatically translate to improved market access.

REPORT ON
VETERINARY MEDICINES

The Veterinary Unit is responsible for assessing the safety, efficacy and quality of veterinary medicines and issuing marketing authorisation for veterinary medicines. The Unit assess 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 compiled annual statistics on consumption of antimicrobial agents for use in animals using the World Organisation for Animal Health (OIE)'s reporting tools. The data was submitted to the OIE and contributed to the 3rd Annual Report on antimicrobial agents intended for use in animals.

Overall median timeline to registration in 2018 was 630 days (21 months) inclusive of the manufacturers' time to respond to queries.

Applications for Veterinary Medicines received in 2018

16

Veterinary Products registered (including prior years)

9

Applications for registration withdrawn

0

Applications Refused Registration (including prior years)

4

REPORT ON
COMPLEMENTARY MEDICINES

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. A total of 89 applications were received from January to December 2018. A total 65 products including those received from prior years were issued approval certificates in 2018. A total of 3 products received in prior years were refused approval. In 2018 the initiative to reclassify vitamin and mineral supplements on the conventional medicines register to complementary medicines commenced. Enforcement activities continued to ensue in removing products that had no provisional or substantive legal authority to access the market. As of December 2018, the Complementary Medicines Unit had one dedicated staff member and a total of 117 complementary medicines had been approved. To access the list of approved medicines, the complementary medicines register was published on the MCAZ website.

Applications for Complementary Medicines received in 2018

89

Complementary medicines approved (including prior years)

65

Applications for approval withdrawn

0

Applications refused approval (including prior years)

3

REPORT ON
LICENSING AND ENFORCEMENT

In 2018, 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

MR RICHARD T. RUKWATA

Head, Licensing & Enforcement

Authorisations for Importation of Unregistered Medicines

The number of section 75 applications processed in 2018 for human use came to a total of 10168, which was an increase of 13.3% from those processed in 2017.

This increase is attributed to the decrease in the number of registered medicines which were imported by wholesale dealers, reportedly, due to economic downturn that was also affecting the pharmaceutical sector.

Five hundred and seven (507) of these section 75 authorisations issued for human medicinal products came from institutions as well as wholesalers importing in bulk.

This was a sharp decrease of 53.4% compared to 2017, when there was one thousand and eighty nine (1 089) applications processed. This was reportedly, due to economic downturn that was also affecting the pharmaceutical sector hence the wholesalers were unable to import medicines on the bulk importation list.

Inspections conducted in 2018

Eight hundred and seventy-seven (877) inspections of licensed premises were carried out by the MCAZ Inspectorate in 2018 compared to nine hundred and sixty (960) in 2017. The decrease was mainly attributed to fuel challenges.

In 2018, eight-one (81) inspections of approved public institutions, mainly rural health centres, were carried out with support from the Health Transition Fund and Global Fund compared to the two hundred and thirty-seven) 237 conducted using the same support in 2017.

The Inspectorate Unit carried out ninety-seven (97) special investigational inspections in 2018 compared to one hundred and forty (140) in 2017.

Regional harmonization & work sharing

The Authority continued to take the leading role in coordinating and leading the SADC ZAZIBONA GMP inspections, as the implementing agency.

MCAZ GMP Inspectorate

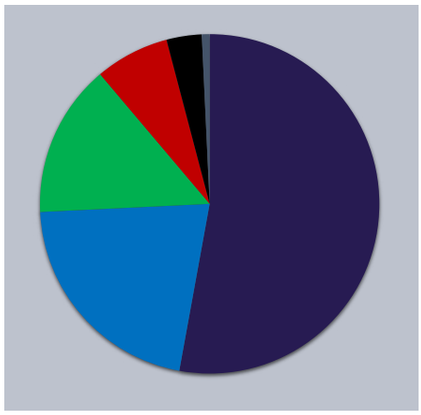
84 Foreign GMP Inspections 7 Local GMP inspections	5 ZaziBoNa GMP Inspections	2 Quality Circle Workshops conducted*

* Capacity building initiative to promote attainment of acceptable GMP standards, thus promoting local production of quality essential medicines

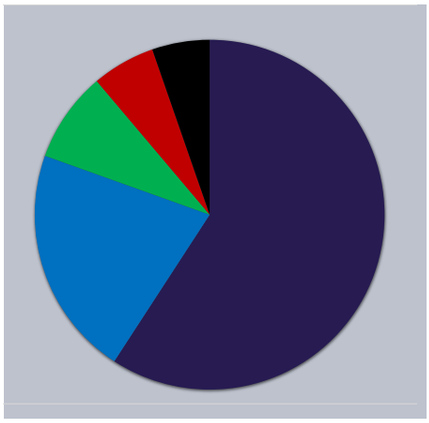
Good Manufacturing Practices (cGMP)

The inspectorate continued with its quality assurance oversight for both local and international manufacturers through Good Manufacturing Practice inspections. Most foreign manufacturers marketing their products in the country are under proactive quality assurance footprint 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 exist for the local industry to meet global standards, the macro-economic challenges have not spared them, as with many industries in the country.

Total Licences and permits	1343
Pharmacy licences	710
Veterinary medicines General Dealers' permits	287
Industrial clinics licences	196
Wholesale dealer's permits	95
Medical practitioner's dispensing licences	45
Manufacturer's licences	10



Total Persons' Licences	1710
Pharmacists licences	1012
Nurses	364
Dispensing Medical Practitioners & Veterinary Surgeons	143
Sales Representative Permits	100
Pharmacy Technicians	91



Other Permits and Licenses

1443	Import Permits issued
258	Number of permits for the importation of precursor substances were issued
182	Number of Approved donations for entry into Zimbabwe
101	Number of licenses to import narcotics and psychotropic substances
95	Export permits issued
72	Number of licences to possess, acquire and administer narcotics, including game capture licences

REPORT ON **PVCT**

MRS PRISCILLA NYAMBAYO

Head, Pharmacovigilance and Clinical Trials

PVCT Division is responsible for:

- Conducting pharmacovigilance activities which include, post-market surveillance of registered medicines, collecting, causality assessment, analysing benefit/risk of adverse drug reaction (ADR) reports and adverse events following immunisation (AEFI) reports.
- Drug information dissemination through publishing drug information bulletin, articles, circulars and alert notices.
- Processing product defects and recalls related to safety aspects.
- Authorisation and monitoring of all clinical trials involving medicines and medical devices that are conducted in Zimbabwe in terms of Part III of the Medicines and Allied Substances Control Act of 1991 [Chapter 15:03].
- Processing of post registration variations, promotional material, and re-instatement applications.
- Processing retentions fees for registered medicines both human products and veterinary products.
- Medicines safety reviews.

571 ICSRs were received in 2018, this was slightly below the number of reports received in 2017 (674). This may be attributed to less number of pharmacovigilance trainings conducted, 3 out of 8 were conducted in 2018. The decrease in number of reports may also be due to the fact that there were no monitoring and evaluation visits to collect the completed reports as well as staff turnover at sites in 2018.

In 2018, only three pharmacovigilance workshops were conducted, one in Bulawayo and two in Harare. One stakeholders' consultative workshop in Harare included reviewing of the Terms of Reference for provincial and district pharmacovigilance centres. The other consultative workshop in Harare was on the new e-ADR reporting system and e-Clinical Trial (CT) application and registry platform. Causality assessment of the reports were done by the Pharmacovigilance and Clinical Trials (PVCT) Committee that is also the national AEFI Committee. Feedback was provided to the health care practitioners through written letters, presentations at the pharmacovigilance workshops and through the medicines bulletin available on MCAZ website.

All the reports received in 2018 were uploaded onto the WHO Vigibase® database. A data cleaning workshop was also conducted in 2018 for ADR reports and serious AEFIs. 801 WHO-Adverse Reactions Terminologies were revised to match with the new Medical Dictionary for Regulatory Activities (MedDRA) terms. The revised report with the new terms was submitted to WHO-Uppsala Monitoring Centre.

Individual Case Safety Reports received in 2018

39 ADRs and Spontaneous Adverse Events (SAEs) received from pharmaceutical industry

66 SAEs from approved Clinical Trials conducted in Zimbabwe

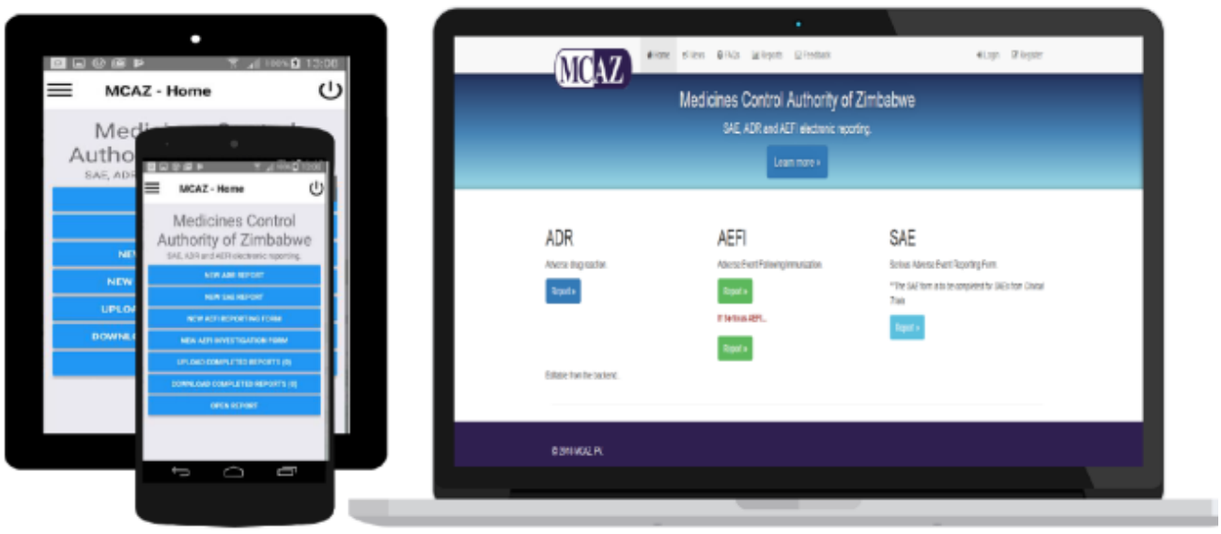
84 Adverse Events Following Immunization (AEFIs)

365 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

16 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

Electronic Adverse Drug Reaction and Clinical Trial Registry System

Funded by The Global Fund to Fight AIDS, Tuberculosis and Malaria



Key features

- Adding convenience to side effects reporting and clinical trial application
- Real time benefit-risk analysis of potential toxicities
- Improved efficiency of medicines safety monitoring
- Online and offline capabilities, which is a plus for areas with limited connectivity
- Environmentally friendly: More cost effective in long term vs current passive paper-based systems.
- Modernisation: Unique innovation in line with current e-health & mobile health innovations.

Targeted Spontaneous Reporting (TSR) program

The Targeted Spontaneous Reporting (TSR) Program for ARVs, anti-TB 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 194 health facilities and 948 health care professionals were trained from 2012 to 2018 in all provinces. The aim of the trainings were to educate, encourage and remind all health care professionals to continuously participate effectively in the reporting of ADRs and preparation of setting up regional pharmacovigilance sites. In 2018 one TSR training was done in Bulawayo. The figure 1 below indicates the total number of TSR reports received by the MCAZ and the reporting professionals in 2018 compared to 2017.

The numbers to the right show that majority of reports in 2018 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. Reporters were sent feedback on the assessments. Feedback on the TSR was included in 2018 bulletin as a way of disseminating information obtained from the reports.

TSR reporting by healthcare

Nurses

228

Pharmacy Staff

75

Medical Doctors

46

Consumers

4

Unknown/other healthcare professionals

12

Inter-country study to assess the inter-rater reliability of the WHO AEFI causality assessment methodology and the utility of the new WHO AEFI causality assessment software

In 2018 the division successfully completed the Inter-country study to assess the inter-rater reliability of the WHO AEFI causality assessment methodology and the utility of the new WHO AEFI causality assessment software. The WHO Global Advisory Committee of Vaccine Safety (GACVS) accepted the results of the study and the WHO –Global Vaccine Safety Initiative (GSVI) then revised the manual and e-tool WHO AEFI causality assessment accordingly. An e-learning course on AEFI causality assessment was launched. Second edition of the AEFI causality assessment manual was published. Upgraded version of the AEFI causality assessment software was developed. India, Zimbabwe and other countries are now using the revised tools, available as second edition of the AEFI causality assessment manual at http://www.who.int/vaccine_safety/publications/gvs_aefi/en/. One can access both the upgraded software as well as the e-learning course at http://gvsi-aefi-tools.org/new/

2018 Publication

"A comparison of Adverse Drug Reaction Profiles in Patients on Antiretroviral and Antitubercular Treatment in Zimbabwe". This was aimed at describing and comparing the adverse drug reaction profiles in patients on highly active antiretroviral therapy only (HAART), HAART and isoniazid preventive therapy (HHART), and HAART and antitubercular treatment (ATTHAART).

[Ref: Masuka, J. T., Chipangura, P., Nyambayo, P. P., Stergachis, A., & Khoza, S. (2018). A Comparison of Adverse Drug Reaction Profiles in Patients on Antiretroviral and Antitubercular Treatment in Zimbabwe. Clinical drug investigation, 38(1), 9-17.]

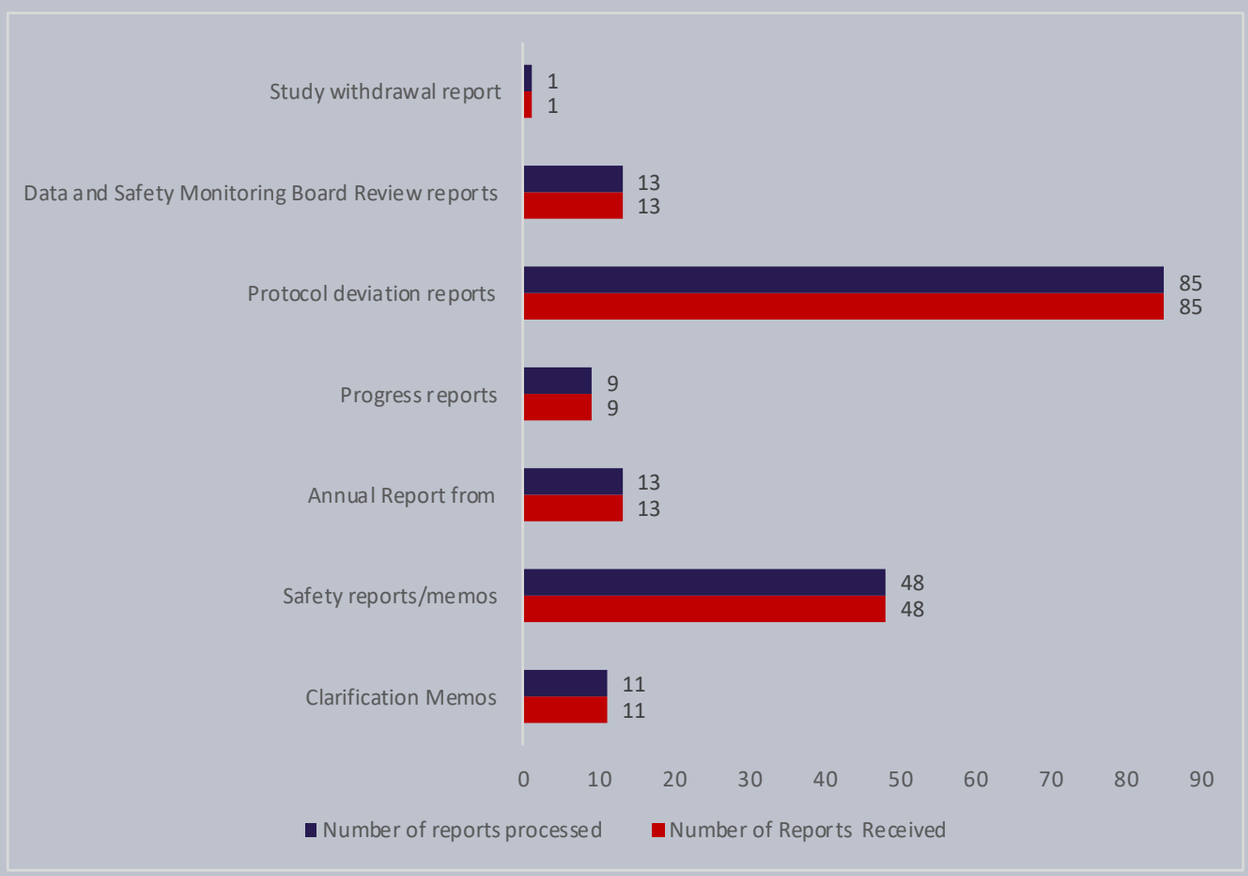
Pharmacovigilance e-modules

The Ministry of Health and Child Care (MoHCC), AIDS and TB Programme, working with key partners in training and clinical mentorship developed an integrated, comprehensive HIV prevention, treatment, care and support package primarily targeting in-service health care workers. The MCAZ through the PVCT division participated in the development of the e- Pharmacovigilance module for the HIV integrated Training which was launched in 2018. The e- Pharmacovigilance module will be used to train health care workers in the country on pharmacovigilance as part of the MoHCC HIV Integrated Training Blended Learning (HIT BL).

2018 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 2018, 5 officers attended GCP training offered by the University Of Zimbabwe College Of Health Science, Research Support Centre. A pre-approval GCP inspection was conducted at AIBST Clinical Trials Unit at Chitungwiza Hospital for three clinical trials. A routine GCP inspection was also carried out at the same facilities for the 2 approved studies. The purpose of the inspections was to ascertain GCP compliance of the approved and proposed studies. Timelines for clinical trials approval were met and submitted to WHO-African Vaccines Regulatory Forum (AVAREF). Ten applications were received in 2018 as compared to sixteen in 2017. All the clinical trial applications received were processed and authorised within the 90 days timeline. 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 table below shows various reports which were received and processed in 2018:



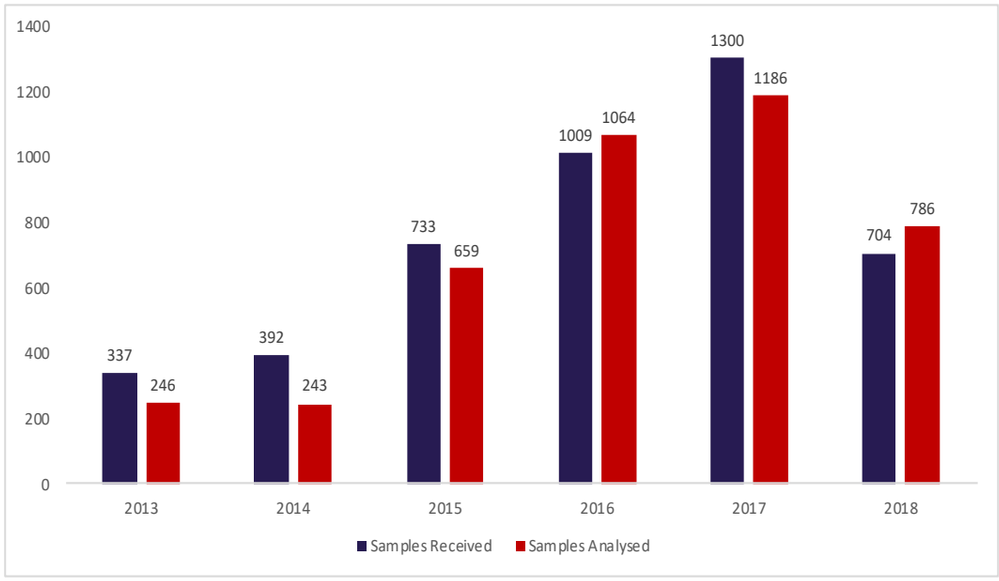
REPORT ON
CHEMISTRY LABORATORY

MRS BRIDGET DUBE
Head, Chemistry Laboratory

The Medicines Control Authority Chemistry Laboratory is a WHO Prequalified and ISO 17025 Accredited laboratory that is actively participating in the National Heath Quality assurance Programme.

Key functions include:

- Pre-distribution analysis of medicines to ensure that quality products are distributed in the medicines supply chain
- Post market surveillance
- Adverse event monitoring in collaboration with the Pharmacovigillance & Clinical Trials Division, by cionducting confirmatory analysis of product defects
- 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.



Trend analysis of samples analysed and Received from 2013 to 2018

RECEIVED
2017 VS 2018
-45%

ANALYZED
2017 VS 2018
-33%

Negative trend can be attributed to quality control testing that was conducted in December 2017, where bulk consignments of donor-funded medicines were received in the country..

Quality Control testing of anti-TB, anti-malarials, anti-retrovirals and essential medicines has been supported by Ministry of Health and Child Care & various donor agencies to ensure safe and good quality products are distributed in Zimbabwe.

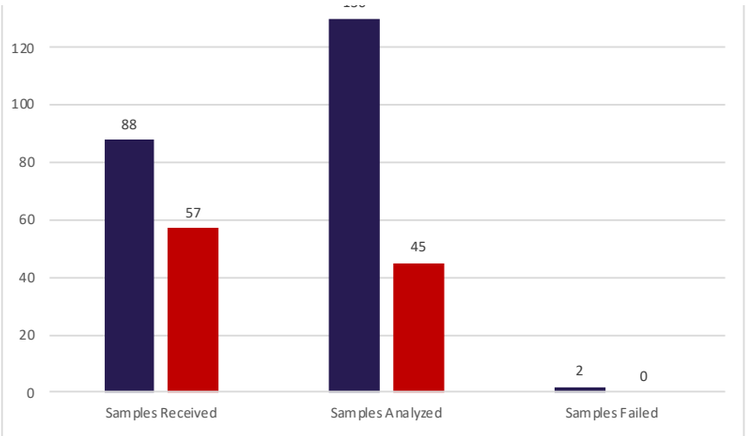
Regional Centre Of Regulatory Excellence (ReCORE) Activities

The Chemistry laboratory managed to train laboratory analyst from Seychelles on Good Practices of Pharmaceutical National Quality Control Laboratories(cGPPCL) guideline.

Inter-laboratory Proficiency Testing

The Chemistry Laboratory participated in two proficiency tesing schemes and performed satisfactorily.

REPORT ON
MICROBIOLOGY AND MEDICAL DEVICES



MR TINASHE GONHO

Manager, Microbiology and Medical Devices

Microbiology Laboratory

The laboratory is responsible for the microbiological analysis of medicines. The laboratory examines sterile and non-sterile pharmaceutical products, complementary medicines, dietary supplements and other allied substances for pathogenic and non-pathogenic microorganisms.

Activities

1. Sample analysis was temporarily suspended mid-2017 because of refurbishment of the laboratory under the UNDP programme.
2. Renovations were done at MCAZ Queensdale premises to allow sample analysis to resume as a temporary measure.
3. The laboratory received fifty-seven (57) samples for testing in the year 2018, and managed to analyse forty-five (45) samples. There was a sudden sharp increase in volume of samples submitted to the laboratory by the Licensing and Evaluation Division towards end of 2018. This resulted in the remaining twelve (12) samples being carried over to the year 2019. There was a 35% decrease in the number of samples received from year 2017 to 2018. This was because the laboratory resumed operations in May 2018. The laboratory has a staff complement of four, the Unit Manager, two analysts and a laboratory hand.

REPORT ON
MICROBIOLOGY AND MEDICAL DEVICES

Medical Devices Laboratory

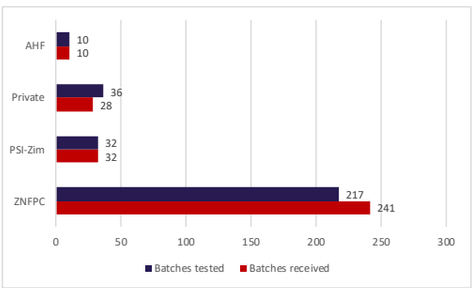
The Medical Devices laboratory does quality conformity assessment of condoms and gloves as guided by MCAZ regulations and international standard requirements. The laboratory is ISO/IEC 17025 accredited for condom testing.

Condoms

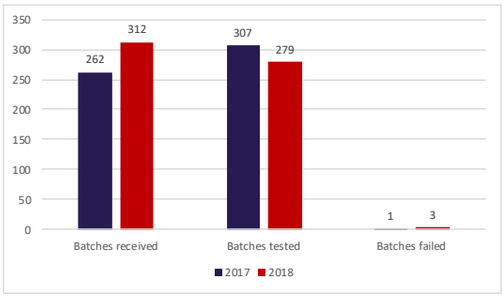
1. The laboratory received five (5) new condom registration applications, and they were all granted market authorisation
2. Three (3) batches of condoms failed quality conformity assessment tests for the period.
3. SADCAS conducted a surveillance audit in March, and the laboratory maintained its accreditation.
4. The laboratory continues to participate in annual proficiency testing schemes coordinated by the FHI360 (USA) and Enersol of Australia.

Gloves

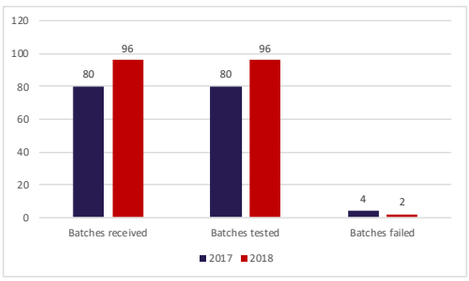
1. The laboratory received and tested ninety-six (96) batches of gloves in year 2018.
2. There was a 20% increase in the number of glove batches received from year 2017 to 2018.
3. The laboratory received six (6) new glove registration applications, and they were all granted market authorisation.
4. Two (2) batches of gloves failed quality conformity assessment tests for the period.
5. The laboratory continues to participate in annual proficiency testing schemes coordinated by Enersol of Australia.



Customer based condom statistics for year 2018



Condom statistics 2017 vs 2018



Gloves statistics 2017 vs 2018

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