MCAZ

Medicines Control Authority of Zimbabwe

2015
Annual Report

MISSION

To protect public health by ensuring that accessible medicines, allied substances and medical devices are safe, effective and of good quality through enforcement of adherence to standards by manufacturers and distributors.

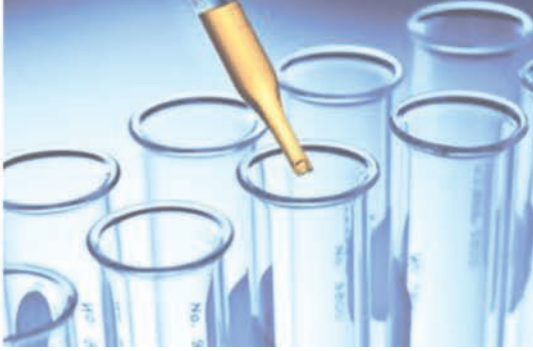
VISION

To be an effective medicines and medical devices regulator in Zimbabwe and a leading regulatory Authority in the world.

CORE VALUES

- High Performance customer focused culture
- Ethical and professional behaviour
- Quality work/products
- Energizing leadership
- Relating performance to rewards
- Teamwork and collaboration
- Wise use of resources
- Integrity and disciplined behaviour
- Continuous improvement
- Social responsibility
- Allegiance and sincerity
- Enhancement of job satisfaction





THE MEDICINES CONTROL AUTHORITY OF ZIMBABWE MANDATE

The Medicines Control Authority of Zimbabwe (MCAZ) formerly the Drugs Control Council was established by the Medicines and Allied Substances Control Amendment Act (No. 1 of 1996) [Chapter 15:03] and became operational in August 1997. The Authority also incorporates the Laboratory, which previously operated as a separate entity. The objective of the amendment was to enable the Authority to operate as a business entity capable of sustaining itself financially, while also fulfilling a statutory mandate.

The mandate of the Authority is to ensure the availability of safe, effective and good quality medicines and medical devices on the Zimbabwean market. This is achieved through the control of the manufacture, distribution, storage and sale of medicines. In addition to the fulfillment of its mandate, in accordance with the Medicines and Allied Substances Control Act (MASCA) the Authority is also mandated to administer the Dangerous Drugs Act on behalf of the Ministry of Health and Child Welfare. Zimbabwe acceded to the following International Drug Conventions, which the Authority also administers.

- The Single Convention on Narcotic Drugs 1961
- The Convention on Psychotropic Substances 1971
- The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1998.

Registered Office

106 Baines Avenue
Harare, Zimbabwe

Postal Address

P.O. Box UA 559
Union Avenue
Harare

Telephone: +263 4 736981-5
Fax: +263 4 736980
Email: mcaz@mcaz.co.zw

AUDITORS

The Auditor General
5th Floor Burrough House
Cnr 4th Street/ George Silundika
PO Box CY 143
Causeway
Harare
Zimbabwe

Telephone: +263 4 793611-4
+263 4 729971-6
Fax: +263 4 728323/5/7
Email: ocag@auditgen.gov.zw

LAWYERS

Honey and Blanckenberg
200 Herbert Chitepo Avenue
Harare
Zimbabwe

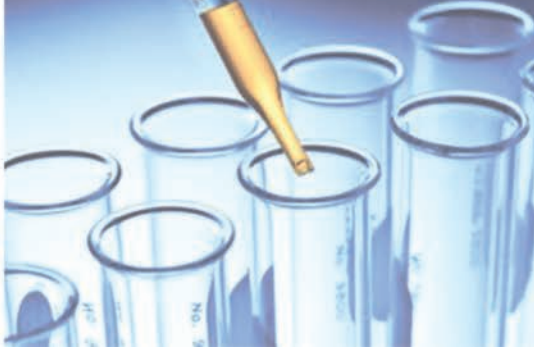
Telephone: +263 4 735280-6
+263 4 732317
+263 4 732398
Fax: +263 4 790013, 792537
Email: admin@honeyb.co.zw

BANKERS

Standard Chartered Bank Zimbabwe Limited
Africa Unity Square Branch
Cnr 2nd Street/ N Mandela Avenue
Harare
Zimbabwe

Telephone: +263 4 706321/5
Fax: +263 4 706314





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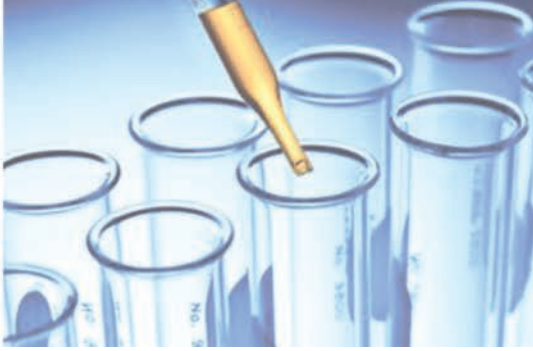
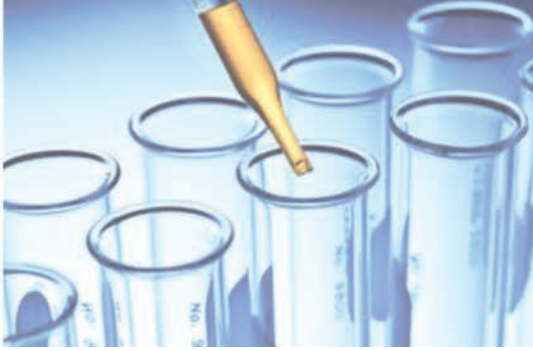


ABBREVIATIONS

ADR	Adverse drug reactions
AEFI	Adverse events following immunizations
AHIC	Animal Health Industry Committee
CEO	Chief Executive Officer
CGF	Corporate Governance Framework
cGMPs	current Good Manufacturing Practices
CTD	Common Technical Document
ERM	Enterprise Risk Management
EVR	Evaluations and Registration
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
HDF	Health Development Fund
HPLCs	High Performance Liquid Chromatography
ICSR	Individual case safety reports
ICT	Information and communications technology
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
NMRAs	National Medicines Regulatory Authorities
PFMA	Public Finance Management Act
PQ	Prequalification Programme
PVCT	Pharmacovigilance and Clinical Trials
QMS	Quality Management System
SADC	Southern African Development Community
SADCAS	Southern Africa Development Community Accreditation Service
SAEs	Serious Adverse Event
SANAS	South African National Accreditation System
TSR	Targeted Spontaneous Reports
USP	United States Pharmacopeia
VAT	Value-Added Tax
ZEPI	Zimbabwe Expanded Programme on Immunization
ZIMRA	Zimbabwe Revenue Authority





CHAIRMAN'S STATEMENT

When we look back at the year 2015, we note that it started on a high note after the constitution of the new MCAZ Board by the Honourable Minister of Health and Child Care, after expiration of the three year term for the previous Board. The new Board and its technical committees will serve for a period of three years. Both the new Board and technical committees have a healthy skills mix from re-appointments and the infusion of new blood. As a result, the meetings of the Board and the committees were characterised by lively and rich deliberation of matters.

In accordance with the recommendation from the Zimbabwe Institute of Directors, the Authority has established a Strategy Committee that gives oversight on strategy formulation, implementation, monitoring and evaluation.

The other significant decision was the resolution to subscribe to Deloitte Tip-Off Anonymous as a way of empowering our customers to blow the whistle should they observe or suspect any unethical conduct or practices by our human capital.

We gazetted the Medicines and Allied Substances Control (Complementary Medicines Regulations) Statutory Instrument 97 of 2015 after approval by the Honourable Minister of Health and Child Care and the Attorney-General's Office. We will hold a stakeholder meeting in January 2016 to ensure that our applicants understand the regulations and the registration guideline.

In the last half of the year, the Authority was advised by the Zimbabwe Revenue Authority (ZIMRA) to apply for value-added tax (VAT) registration and thereafter charge, collect and remit 15% VAT on most of its statutory fees. The Authority engaged tax consultants, accounting firms and the ZIMRA to understand the applicability of VAT to statutory fees and to communicate the adverse effect this will have of increasing the cost of compliance for the industry and ultimately the cost of medicines for the consumer. The Authority looks forward to zero-rating of the statutory fees.

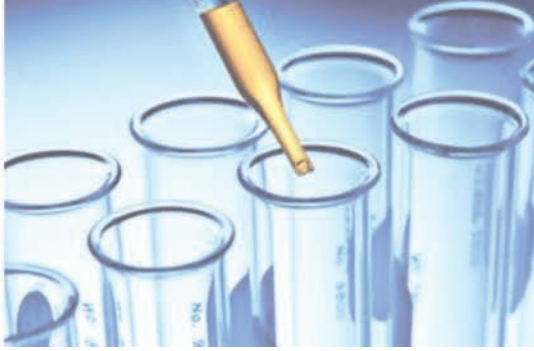
The Authority and its technical committees accomplished their strategic objectives according to the annual plans. We managed to collect the revenue, at cost-recovery level, from the statutory services we provide. Welcome support from developmental partners also assisted in accomplishing the strategic objectives. We thank the Ministry of Health and Child Care (MoHCC) and the collaborating developing partners: Global Fund programme run by UNDP Zimbabwe, Health Transition Fund coordinated by UNICEF and United States Pharmacopoeia (USP) Technical Assistance Programme. We also thank WHO Prequalification Programme (WHO PQ), Health Canada, US-FDA Regulatory Fora for providing training opportunities for our assessors. We also thank the National AIDs Council who assisted the Authority in re-capitalising the condom-testing unit by procurement of condom testing equipment.

The Board and Management upheld their commitment to the SADC Harmonisation Process by supporting the ZAZIBONA Collaboration as the nidus for the gradual regulatory harmonisation of all the 15 member states in the SADC region. Our appreciation goes to WHO PQ Technical Support team that provided technical support in joint evaluation and joint inspection programmes. They also provided quality assurance to ZAZIBONA work.

We observed an increase in the incidences of infractions of the Medicines and Allied Substances Control Act [15:03] and Regulations by licenced persons and facilities. The Authority had to invoke severe regulatory actions on licensed persons and facilities, including suspension and cancellations of licences, to ensure safety of the public. This was necessary, as we prioritise patient safety above all other considerations.

I am proud to say that we managed to achieve all our objectives and deliver on our mandate in 2015. We stayed afloat in the challenging economic environment. As the Chairman of the Authority, I want to thank all members of the Board, Management and staff for the work they carried out in 2015, for their efforts and their wealth of ideas, for their courage to enforce regulatory standards with impartiality in a society facing significant socio-economic challenges that create a fertile ground for unethical practices.





As an Authority, we want to continue to make progress together to the benefit of the public that depend on us: our commitment and expertise ensuring the safety, quality and efficacy of the medicines they take.

J. C. Ncube (Mrs)

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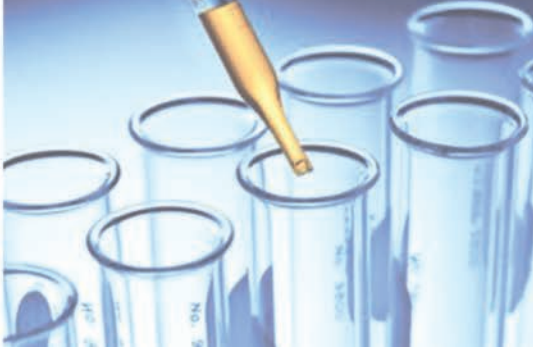


Our vision, mission and values carried us through the year 2015.

Customer-focus

The Authority maintained customer-engagement through the scheduled Human Pharmaceutical Sector and the Veterinary Pharmaceutical Sector liaison meetings. We also held special consultative meetings with industry, to discuss new regulations such as the Medical Devices Regulations and new guidelines such as the Guidelines for Registration of Veterinary Medicines. Our responsiveness ensures that we formulate and enforce legislation that addresses real issues on the ground. The customer engagement ensures high levels of understanding of our guidelines, commitment and compliance from industry.

We also launched web 2.0 technologies for engagement with the general public. We are now reachable on Facebook and Twitter. In line with our government's policy objectives for financial inclusion, we also introduced alternative payment modes whereby MCAZ customers could make payments using mobile telephone platforms. An MCAZ 'Ecocash' account was opened with Econet Mobile Telephone Company. In addition, we expanded our public education programme to empower the general public to question the poverty and ignorance driven practice of purchasing unregistered medicines from unlicensed persons and unlicensed premises. The Medicines Control Authority of Zimbabwe continued reaching the public over radio and television. In addition, billboards with consumer advice were installed at strategic public places. We continued to assess the impact of the interventions. Our appreciation goes to the Health Transition Fund Programme which assisted us in the generation of the information, education and communication materials.

In December 2015, we held a stakeholder forum for all our key stakeholders. The Authority presented highlights and distributed copies of the 2014 annual report which included the audited financial reports. Further a long service award ceremony for staff members that had completed five, ten, fifteen, and twenty years of continuous service was held.

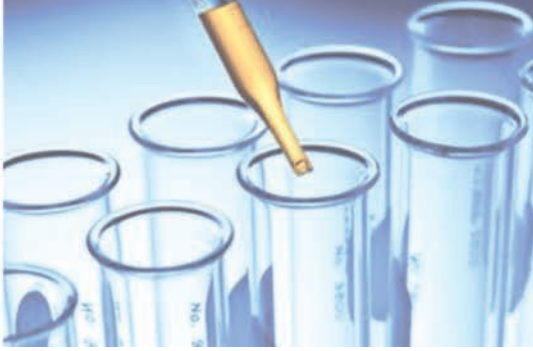
Continuous improvement

We managed to transition from accreditation by the South African National Accreditation Systems (SANAS) to Southern African Development Community Accreditation Systems (SADCAS) for the ISO 17025 Management System. The Authority now has a three year SADCAS accreditation to ISO 17025 running from 7 August 2015 to 6 August 2017. We will continue to receive surveillance monitoring visits from SADCAS. MCAZ maintained the WHO Prequalification status for the Chemistry Division. In 2015, we also participated in Proficiency Testing schemes for the Chemistry Division and the Medical Devices and Microbiology Unit. Our performance, benchmarked against other similar laboratories on the continent and beyond, was satisfactory.

The ZAZIBONA Collaboration was formally recognised and adopted by the SADC Health Minister's Conference as a SADC initiative. This means that, henceforth, other SADC members are able to join ZAZIBONA. ZAZIBONA caters for the needs of both fully functional and upcoming national medicines regulatory authorities (NMRAs). Functional SADC NMRAs will 'actively' participate in joint dossier review and GMP inspection. Other NMRAs still in the formative phases will have access to relevant training sessions, databases of evaluation and GMP inspection reports, fellowship and twinning opportunities with more functional NMRAs. The Ministers agreed that as new members joint the programme, it will keep the original brand name 'ZAZIBONA' as it had already acquired international acclaim and recognition as a unique regulatory harmonisation model. The ZAZIBONA process is designed to bring unprecedented benefits to applicants and participating resource limited NMRAs. Applicants have opportunities: to submit copies of a single harmonised SADC CTD dossier, to receive a single consolidated list of queries and realise compressed time to registration and simultaneous market access in participating countries. The ZAZIBONA process provides all the stated benefits without compromise to the applicant's right to confidentiality.

The Authority hosted a training workshop on advanced causality assessment with the support of WHO. We also hosted the International Atomic





Energy training on evaluation of dossiers for radio-pharmaceutics. Our managers continue to receive training on people and self-management skills. The results of the (internal and external) customer satisfaction survey conducted by the University of Zimbabwe Business School were produced and discussed in 2015. Useful feedback was attained and was positive on the whole. However, some opportunities for further improvement were identified. Functional Units were requested to propose and implement gap-closing measures for specific gaps identified in their area, while organisation-wide gap-closing measures were proposed and implemented for general issues. The Authority, therefore, has baseline data on internal and external customer satisfaction and will monitor from the baseline. The internal customer satisfaction index from the consultancy tallied well with the results of an internal staff satisfaction survey.

In response to the growth of the number of new applications, we filled all the vacant posts in the Evaluations and Registration Division. A further eight part-time dossier assessors were hired, trained and deployed. The effect of the additional manpower is expected to assist the Division to deal with the backlog and improve timelines.

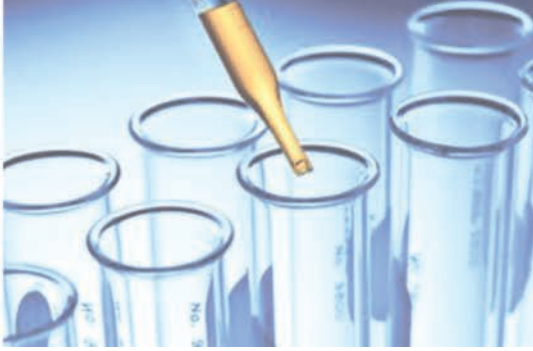
The productivity of the Chemistry laboratory has increased phenomenally over the years. Our laboratory which used to be viewed as a cost-centre has now been transformed to one of the most productive business units of the Authority.

Performance Against Strategic Plan

The progress made against the strategic goals for 2015 is presented on three levels; target not met, on track or narrowly missed and target met.

Key Result Area (KRA)	Strategic Goal	Progress		
		Target not met	On track	Target met
KRA 1 Adequate Resources Base	Goal: To increase income by 20%			
	Goal 2: To mobilise US$0.5M from partners			
	Goal 3: To reduce resource utilisation from 95% to 94%.			
KRA 2 Effective Automated Systems	Goal 4: To increase the automation of key business processes from an estimated 30% to 50%.			
KRA 3 Effective Regulatory Process	Goal 5: To improve process meeting set timelines from an estimated 40% to 60%.			
	Goal 6: To improve our regulatory compliance from 65% to 70% of the WHO assessment tool by 2018			
KRA 4 Skilled and Competent People	Goal 7: To improve skills retention from an estimated 60% to 70%.			
	Goal 8: To reduce the competency gap from an estimated 10% to 7%.			
KRA 5 Good Corporate Governance	Goal 9: To have achieved 75% of all defined certifications (ISO 17025, WHO PQ and ISO 9001).			





Key Result Area (KRA)	Strategic Goal	Progress		
		Target not met	On track	Target met
	Goal 10: To be designated for 60% of our regulatory functions as a centre of excellence. Goal 11: To achieve 100% compliance to the			
	Corporate Governance Framework for State Enterprises and Parastatals and Public Finance Management Act.			
KRA 6	Goal 12: To improve customer satisfaction from an estimated 55% to 75%.			
Value for Money Services	Goal 13: At least 10% of urban population (high school and above) should know about MCAZ.			

Although an increase in resources from revenue from statutory fees, investments, and partners exceeded the targets for 2015, the resource utilisation (expenditure) is still higher that the target of 94% for 2015. Additional cost cutting measures would be implementing in the subsequent years to meet the targets for resource utilisation set in the strategic plan. The estimated baseline competency gap of 10% underestimated the actual competency gap (20%) based on the comprehensive staff skills gap analysis performed in 2015. Thus, the target for 2015 was not met, however, measures have been put in place to ensure the target is met at the end of the strategic plan period. Progress towards ISO 9001 certification for the whole organization is on track. The MCAZ Chemistry and Medical Devices Unit laboratories are now accredited by SADCAS from August 2015 to August 2020 - ISO 17025, while the Chemistry retained the WHO Prequalificatn status.

Integrity and Accountability

The MCAZ Anti-Corruption Policy and Code of Ethics were approved by the Board in 2015. The policies are applicable to Board & Committee Members and Authority staff members. Copies of the documents were distributed to all Authority staff members during the first quarter of 2015. Furthermore the Authority agreed that MCAZ subscribes to the Deloitte Tips Off Anonymous whistle-blowing systems to detect, deter and expose any unethical practices by our staff members.

G. N. Mahlangu (Ms)

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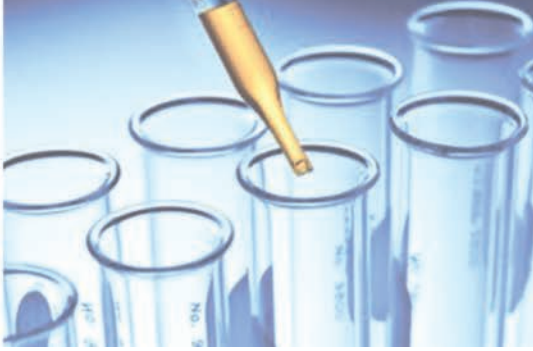
MCAZ DIRECTOR-GENERAL





GOVERNANCE AND RISK REPORT

Growing organizations, such as the Medicines Control Authority of Zimbabwe that are also in evolving industries, require effective and systematic governance structures which enable them to optimally and effectively utilize their entire resource base. The Authority is also cognizant that for governance to act as an enabler in business, continuous monitoring of the governance structure is imperative to ensure optimum process flows and to prevent any possible transgressions in the organization. To that end, the Authority has in place an established and effective governance structure to ensure sound leadership, direction, oversight, and control of the organization in order to make certain that its strategic objectives are achieved, and that there is proper accounting for the conduct of its affairs, the use of its resources, and the results of its activities.

The Board 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 such as 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. This enables the Authority's stakeholders to derive the assurance that in executing its national mandate the Authority is being managed ethically, and resources are being utilized effectively and efficiently for the benefit of all its stakeholders.

The Authority is required by the MASCA, PFMA and the CGF to produce annual audited financial statements. The Authority has managed to produce clean audited financial statements over the years. The 30 June deadline to produce the statements however remains a challenge and the Board is committed to ensuring that this important deliverable is met in future years.

The Board of Directors

The Board is currently comprised of 11 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.

MEMBER	MASCA SECTION UNDER WHICH APPOINTMENT IS MADE	DATE APPOINTED
Mrs J. Ncube (Chairman)	Section 4(2)(e) Law Society)	01/11/2014
Dr. A. F. Zinanga (Vice Chairman)	Section 4(2)(a) (Medical Association)	01/11/2014

MEMBER	MASCA SECTION UNDER WHICH APPOINTMENT IS MADE	DATE APPOINTED
Dr. P Muvavarirwa	Section 4(2) (b) (Council of Vet. Surgeons)	01/11/2014
Mrs J. Chaibva	Section)4(2)(c) (Pharmaceutical Society)	01/11/2014
Dr. P. Chonzi	Section 4(2)(d) (Local Authority)	01/11/2014
Dr. R. Gwisai	Section 4 (2)(f) (Specialist Physician)	01/11/2014
Dr. C Pasi	Section 4 (2)(g) (Knowledge of action and application of medicines)	01/02/2015
Mrs. R Hove	Section 4 (2)(h) (Ministry of Health)	01/11/2014
Prof. C.C. Maponga	Section 4(1) (Any other)	01/11/2014
Mr. J Kunonga	Section 4(1) (Any other)	01/02/2015
Mr. D Mandishona	Section 4(1) (Any other)	01/02/2015
Mrs. D. Mandaza	Legal Adviser	

The Board is responsible for directing the operations of the Authority to achieve its mandate through the establishment of strategies objectives, key policies and management structures. During the year Board meetings were not only focused on reviewing past performance but also on debating new strategies, policies and decisions to ensure that set targets are realised.

The Board meets at least quarterly to evaluate performance, assess risks and holds additional meetings where necessary to shape the strategic direction of the Authority and its review.

The Director-General who is the CEO of the Authority is the Head of the Secretariat.
The Director-General is responsible for the day-to-day management of the organization with all powers, discretions and delegations authorised, from time to time, by the Board.
Members of the Board or its Committees are required to declare any interest before the commencement of meetings and in line with best practice, members who declare their interests are expected to recuse themselves from any deliberations made related to the interests declared.

Board Committees

Certain responsibilities and functions of the Board are delegated to various committees whose members are skilled and competent. However, the Board retains full accountability for decisions made. All committees have written terms of reference that are reviewed annually and changes made where necessary. Minutes of Committee meetings are circulated and reported on at the subsequent Board meeting.

Individuals with specific qualifications and experience, who are not members of the Board are co-opted into Board Committees to provide diversity and add depth to the quality of Committee debates. All Board Committees are chaired by a member of the Board and members of the Management Team attend meetings as appropriate.

In line with good Corporate Governance, the following Board Committees have been established:

Audit Committee

The Committee's primary functions are to assist the Board in its evaluation and review of the adequacy and efficiency of the internal control systems, accounting practices, information systems and audit

processes applied in the day-to-day management of the Authority's business, and to introduce measures to enhance the credibility and objectivity of financial statements and reports prepared with reference to the affairs of the Authority.

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 organisational structure is in place to achieve the Authority's goals.

Finance Committee

The Authority is required to maintain adequate accounting records and prepare financial statements according to generally accepted accounting standards. The Finance Committee which helps the Authority achieve this, sits quarterly to review the management accounts. This Committee also assists the Board in ensuring that financial resources are budgeted, and utilized prudently in the most effective and efficient manner, contributing towards the organization's overall mission, objectives and strategies.

In addition to the above Committees, the following committees are also in existence in accordance with section 11 of MASCA: Executive, Hearing, Legal, Laboratory, Licensing and Advertising, Veterinary, Pharmacovigilance and Clinical Trials and Registration.

Technical Committees

In accordance with section 11 of MASCA, the Authority has technical committees such as Hearing, Legal, Laboratory, Licensing and Advertising, Veterinary, Pharmacovigilance and Clinical Trials and Registration that are responsible for the decision making on behalf of the Authority. The committees are made up of external experts with relevant qualifications and experience appointed by the Authority in liaison with the Minister of Health and Child Care. The committees are chaired by an Authority Member who reports back to the Authority every quarter. The decisions of the committees are ratified by the Authority. Landmark decisions made by the Committees are discussed to inform policy in the ever-changing regulatory landscape.

Board and Committee Attendance (From 1 January 2015 to 31 December 2015)

NAME OF MEMBER	BOARD		AUDIT COMMITTEE		HR COMMITTEE		FINANCE COMMITTEE	
	Attended	Possible	Attended	Possible	Attended	Possible	Attended	Possible
Mrs. J. Ncube	3	4	N/A	N/A	2	4	N/A	N/A
Dr. A. F. Zinanga	4	4	N/A	N/A	N/A	N/A	5	5
Dr. P Muvavarirwa	4	4	1	1	4	5	5	5
Mrs J. Chaibva	4	4	3	4	N/A	N/A	N/A	N /A
Dr. P. Chonzi	4	4	3	4	1	1		
Dr. R. Gwisai	4	4			4	4		
Dr. C Pasi	4	4						
Mrs. R. Hove	3	4						
Dr. C.C. Maponga	3	4			1	1	1	1
Mr. J Kunonga	4	4	3	3	3	3	1	4
Mr. D Mandishona	3	4					2	4
Mrs. D. Mandaza	4	4						

NAME OF MEMBER	BOARD		AUDIT COMMITTEE		HR COMMITTEE		FINANCE COMMITTEE	
	Attended	Possible	Attended	Possible	Attended	Possible	Attended	Possible
Mr. C. F. Dube			4	4				
Mr. F. Gwiza			4	4				
Mr. C. D Mahofa			3	3				
Mr. E. Jinda					3	4		
Mrs. R Nhamo					3	3		
Mr. M Nguwi					3	3		
Mr. I Ruzengwe							2	4
Mr. C Shoniwa							2	4

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.

Board Members' Remuneration

The remuneration of the Board and its Committee members is approved by the Minister.

The Management Team

The management team is listed in the table below;

NAME	POSITION
Ms G.N. Mahlangu	Director - General
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
Mrs. A Chikowore	Quality Manager
Mr T. Gonho	Manager- Medical Devices and Micro- Biology Unit
Mr T. Munhenga	Human Resources Manager
Mrs M.A. Maunga	Legal Manager *(Up to 30 June 2015)*
Ms. C Mugwira	Legal Manager *(From 01 September 2015)*
Mr H. Ngwarai	Head of Internal Audit Unit
Mr T Nyovhi	ICT Manager (*From 01 May 2015)*
Mr A.F. Dzinamarira	Accountant

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.

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. The policy documents were distributed to all Authority staff members during the first quarter of 2015.

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.

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.

AUDITED FINANCIAL STATEMENT

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, 2015.

Report on the Consolidated Financial Statements

I have audited the accompanying consolidated financial statements of Medicines Control Authority of Zimbabwe and its subsidiary as set out on pages 17 to 32 which comprise the consolidated statement of financial position as at December 31, 2015, and the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, and the notes to the consolidated financial statements, including a summary of significant accounting policies and other explanatory notes.

Director's Responsibility for the Consolidated Financial Statements

The Authority's directors are responsible for the preparation and fair presentation of the 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]. This responsibility also includes: designing, implementing and maintaining internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

Auditor's Responsibility

My responsibility is to express an opinion on these consolidated financial statements based on my audit. I conducted my audit in accordance with International Standards on Auditing (ISAs) and International Standards of Supreme Audit Institutions (ISSAIs). Those standards require that I comply with ethical requirements and plan and perform the audit to obtain reasonable assurance whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements 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. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

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

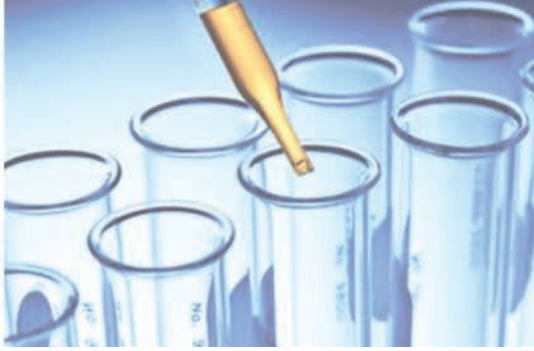
Opinion on the consolidated financial statements

In my opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Medicines Control Authority of Zimbabwe as at December 31, 2015, and the consolidated financial performance and the consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards.

Opinion on the Authority's financial statements

In my opinion, the Authority's financial statements present fairly, in all material respects, the financial position of Medicines Control Authority of Zimbabwe as at December 31, 2015, and its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards.





Report on other legal and regulatory requirements

In my opinion, the consolidated 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.

July 19 , 2017.

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M. Chiri,
AUDITOR-GENERAL.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE (MCAZ)
CONSOLIDATED STATEMENT OF FINANCIAL POSITION
As At December 31, 2015

	Note	MCAZ GROUP		AUTHORITY	
		2015 US$	2014 US$ Restated	2015 US$	2014 US$ Restated
Assets					
Non-current assets		4,586,583	4,824,982	4,305,178	4,543,577
Property, plant and equipment	4	2,686,044	2,986,482	2,686,044	2,986,482
Investment properties	5	1,838,500	1,838,500	1,338,500	1,338,500
Investment in subsidiary	6	-	-	218,595	218,595
Financial assets		62,039	-	62,039	-
Current assets		973,774	909,969	961,933	920,709
Inventories	7	24,394	37,421	24,394	37,421
Trade and other receivables	8	471,164	304,280	492,595	323,162
Cash and cash equivalents	9	478,216	568,268	444,944	560,126
Total assets		**5,560,357**	**5,734,951**	**5,267,111**	**5,464,286**
Reserves and liabilities					
Reserves		**4,465,346**	**4,422,067**	**4,387,673**	**4,354,009**
Capital reserve		5,234,444	5,234,444	5,444,017	5,444,017
Accumulated Fund		(769,098)	(812,377)	(1,056,344)	(1,090,008)
Non controlling interest		199,291	199,199	-	-
Non-current liabilities		**514,176**	**620,334**	**505,038**	**611,699**
Deferred income	10	496,048	605,274	496,048	605,274
Deferred tax		9,138	8,635	-	-
Staff vehicle contribution scheme		8,990	6,425	8,990	6,425
Current liabilities		**381,544**	**493,351**	**374,400**	**498,578**
Trade and other payables	11	252,474	395,757	252,474	400,984
Dividend payable		4,100	-	-	-
Tax payable		3,044	-	-	-
Leave pay provision		121,926	97,594	121,926	97,594
Total reserves and liabilities		**5,560,357**	**5,734,951**	**5,267,111**	**5,464,286**

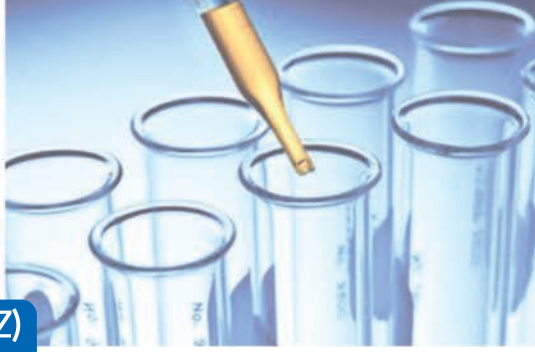
17 July, 2017.

G.N. Mahlangu,
(DIRECTOR- GENERAL).

17 July, 2017.

J. Ncube,
(CHAIRMAN).





MEDICINES CONTROL AUTHORITY OF ZIMBABWE (MCAZ)
CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
for the year ended December 31, 2015

	Note	MCAZ GROUP		AUTHORITY	
		2015 US$	2014 US$	2015 US$	2014 US$
INCOME		**4,145,603**	**3,933,547**	**4,115,503**	**3,911,379**
Medicines control income	12	3,013,778	3,052,979	3,013,778	3,052,979
Laboratory services income	13	486,384	204,652	486,384	204,652
Other income	14	645,441	675,916	615,341	653,748
EXPENDITURE		**4,094,586**	**4,459,300**	**4,081,839**	**4,337,305**
Other expenses	15	2,302,490	2,097,201	2,302,490	2,097,201
Administration costs	17	1,792,096	2,362,099	1,779,349	2,240,104
Surplus/ (deficit) for the year		**51,017**	**(525,753)**	**33,664**	**(425,926)**
Taxation		**(3,546)**	**4,648**	**-**	**-**
Other Comprehensive Income		**-**	**-**	**-**	**-**
Total comprehensive income / (loss)		**47,471**	**(521,105)**	**33,664**	**(425,926)**
Surplus/ (deficit) attributable to:					
Equity holders of the parent		43,279	(482,294)	-	-
Non controlling interests		4,192	(38,811)	-	-
Surplus for the year		47,471	(521,105)	33,664	(425,926)

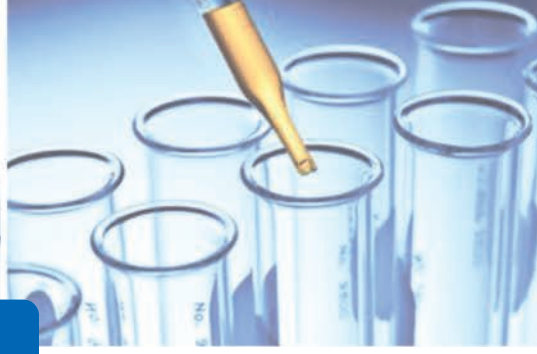


MEDICINES CONTROL AUTHORITY OF ZIMBABWE
STATEMENT OF CHANGES IN RESERVES
for the year ended December 31, 2015

Consolidated	Revaluation Reserve US$	Accumulated Fund US$	Capital Reserve US$	Total US$	Non Controlling Interest US$	Total Equity US$
Balance as at January 1, 2014	599,595	(177,213)	5,234,444	5,656,826	234,637	5,891,463
Deficit for the year	-	(482,294)	-	(482,294)	(38,811)	(521,105)
Balance as at December 31, 2014	599,595	(659,507)	5,234,444	5,174,532	195,826	5,370,358
Balance as at December 31, 2014	599,595	(659,507)	5,234,444	5,174,532	195,826	5,370,358
Prior period adjustment	(599,595)	(152,870)	-	(752,465)	3,373	(749,092)
Restated balance as at January 1, 2015	-	(812,377)	5,234,444	4,422,067	199,199	4,621,266
Surplus for the year	-	43,279	-	43,279	4,192	47,471
Dividend	-	-	-	-	(4,100)	(4,100)
Balance as at December 31, 2015	-	(769,098)	5,234,444	4,465,346	199,291	4,664,637

Authority	Revaluation Reserve US$	Accumulated Fund US$	Capital Reserve US$	Total US$
Balance as at January 1, 2014	381,404	(296,773)	5,444,017	5,528,648
Deficit for the year	-	(425,926)	-	(425,926)
Balance as at December 31, 2014	381,404	(722,699)	5,444,017	5,102,722
Balance as at December 31, 2014	381,404	(722,699)	5,444,017	5,102,722
Prior period adjustment	(381,404)	(367,309)	-	(748,713)
Restated balance as at January 1, 2015	-	(1,090,008)	5,444,017	4,354,009
Deficit for the year	-	33,664	-	33,664
Balance as at December 31, 2015	-	(1,056,344)	5,444,017	4,387,673





MEDICINES CONTROL AUTHORITY OF ZIMBABWE
CONSOLIDATED STATEMENT OF CASH FLOWS
for the year ended December 31, 2015

	Note	MCAZ GROUP		AUTHORITY	
		2015 US$	2014 US$	2015 US$	2014 US$
Net cash flow from operating activities		**50,582**		**21,352**	**201,253**
Surplus for the year		51,017	(525,753)	33,664	(425,926)
Adjusted for non cash items:		**289,561**	**669,687**	**292,604**	**566,865**
Depreciation	4	421,225	402,926	421,225	402,926
Taxation		(3,043)	3,330	-	-
Increase in provision for leave pay		24,332	22,665	24,332	22,665
Fair value adjustment on investment property		-	391,250	-	291,250
Deferred income	10	(110,516)	(115,154)	(110,516)	(115,154)
Loss/(profit) on disposal of property, plant and equipment		(17,159)	668	(17,159)	668
Interest earned		(25,278)	(35,998)	(25,278)	(35,490)
Working capital changes:		**(289,996)**	**64,952**	**(304,916)**	**60,314**
Decrease/ increase in inventory		13,027	(1,258)	13,027	(1,258)
Increase/ (decrease) in trade and other receivables		(166,884)	13,251	(169,433)	(10209..)
Decrease/increase in trade and other payables		(136,139)	52,959	(148,510)	71,781
Net cash flow from investing activities:		**(139,099)**	**(141,627)**	**(139,099)**	**(142,135)**
Purchase of property, plant and equipment		(134,145)	(194,805)	(134,145)	(194,805)
Purchase of financial assets		(62,039)	-	(62,039)	-
Proceeds from disposal of property, plant and equipment		31,807	17,180	31,807	17,180
Interest received		25,278	35,998	25,278	35,490
Net cash flow from financing activities:		**(1,535)**	**6,425**	**2,565**	**6,425**
Dividend paid		(4,100)	-	-	-
Staff vehicle contributions		2,565	6,425	2,565	6,425
Net Increase/(decrease) in cash and cash equivalents		**(90,052)**	**73,685**	**(115182..)**	**65,543**
Cash and cash equivalents at beginning of the year		**568,268**	**494,583**	**560,126**	**494,583**
Cash and cash equivalents at year end	9	**478,216**	**568,268**	**444,944**	**560,126**

1. NATURE OF BUSINESS

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

2. BASIS OF PREPARATION

2.1.1 Statement of compliance

The consolidated financial statements for the year ended December 31, 2015, have been prepared in conformity with International Financial Reporting Standards promulgated by the International Accounting Standard Board (IASB).

2.2 Basis of measurement

The Group's financial statements are based on the statutory records that are maintained under the historical cost basis, except for the following material items in the statement of financial position:

- Available-for-sale financial assets are measured at fair value;
- Investment property is measured at market value;

2.3 Functional and presentation currency

The Group's financial statements are presented in United States Dollar (US$) which is the Group's functional currency. All the financial information presented has been rounded to the nearest dollar.

2.4. Critical accounting judgments, assumptions and estimates

In preparing the financial statements, management is required to make estimates and assumptions that affect the amounts presented in the financial statements and related disclosures. Use of available information and the application of judgment is inherent in the formation of estimates. Actual results in the future could differ from these estimates which may be material to the financial statements. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimates are revised and in any future periods affected. Significant judgments include the following:

2.4.1 Useful lives and residual values of property, plant and equipment

The Group assesses useful lives and residual values of Property, Plant and Equipment each year taking into account past experience and technology changes. The depreciation rates are set out in note 3.1.2 and no changes to these useful lives have been considered necessary during the year. Management has set residual values for all classes of property, plant and equipment at nil.

2.5 New standards, amendments and interpretations issued but not effective for the financial year beginning January 1, 2015 and not early adopted

The Authority did not adopt any new or revised accounting standards or interpretations in the current year that could have had an impact on the amounts or disclosures reported in these financial statements.

i. IFRS 9 Financial Instruments effective January 1, 2018

a. Classification and measurement of financial assets

All financial assets are measured at fair value on initial recognition, adjusted for transaction costs if the instrument is not accounted for at fair value through profit or loss (FVTPL). Debt instruments are subsequently measured at FVTPL, amortised cost or fair value through other comprehensive income (FVOCI), on the basis of their contractual cash flows and the business model under which the debt instruments are held.

There is a fair value option (FVO) that allows financial assets on initial recognition to be designated as FVTPL if that eliminates or

significantly reduces an accounting mismatch. Equity instruments are generally measured at FVTPL.

However, entities have an irrevocable option on an instrument-by-instrument basis to present changes in the fair value of non-trading instruments in other comprehensive income (OCI) (without subsequent reclassification to profit or loss).

b. Classification and measurement of financial liabilities

For financial liabilities designated as fair value through profit or loss (FVTPL) using the fair value option (FVO), the amount of change in the fair value of such financial liabilities that is attributable to changes in credit risk must be presented in other comprehensive income (OCI). The remainder of the change in fair value is presented in profit or loss, unless presentation of the fair value change in respect of the liability's credit risk in OCI would create or enlarge an accounting mismatch in profit or loss.

IAS 39 Financial Instruments: Recognition and Measurement classification and measurement requirements for financial liabilities have been carried forward into IFRS 9, including the embedded derivative separation rules and the criteria for using the FVO.

c. Impairment

The impairment requirements are based on an expected credit loss (ECL) model that replaces the IAS 39 incurred loss model. The ECL model applies to: debt instruments accounted for at amortised cost or at FVOCI; most loan commitments; financial guarantee contracts; contract assets under IFRS 15; and lease receivables under IAS 17 Leases.

ii. IFRS 15 Revenue from Contracts with Customers

IFRS 15 replaces all existing revenue requirements in IFRS (IAS 11 Construction Contracts, IAS 18 Revenue) and applies to all revenue arising from contracts with customers. It also provides a model for the recognition and measurement of disposal of certain non-financial assets including property, equipment and intangible assets.

The standard outlines the principles an entity must apply to measure and recognise revenue. The core principle is that an entity will recognise revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to a customer.

The standard is effective for accounting periods beginning on or after January 1, 2018, however early adoption is permitted.

2.6 Basis of Consolidation

2.6.1 Group

The consolidated financial statements comprise the financial statements of the Group and its subsidiary as at 31 December 2015.

2.6.2 Subsidiary

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

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

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

Non-controlling interests represent the

portion of the profit or loss and net assets not held by the Group, and are presently disclosed in profit or loss and within equity in the Group statement of financial position, separate from parent shareholders' equity. Non-controlling interests are measured at its proportionate share of the net assets acquired.

2.6.2.1 Change in degree of control

A change in the ownership interest of a subsidiary, without loss of control, is accounted for as an equity transaction.

2.6.2.2 Loss of Control

If the Group loses control over a subsidiary, it;

- Derecognises the assets (including goodwill) and liabilities of the subsidiary;
- Derecognises the carrying amount of any non-controlling interest;
- Derecognises the cumulative transaction differences recorded in equity;
- Recognises the fair value of any investment retained;
- Recognises any surplus or deficit in profit or loss;
- Recognises the fair value of the consideration received;
- Reclassifies the parent's share of components previously recognised in other comprehensive income to profit or loss or retained earnings, as appropriate.

3 ACCOUNTING POLICIES

The accounting policies applied in the preparation of these financial statements are consistent with those applied in the financial statements for the year ended December 31, 2014.

3.1 Property, Plant and Equipment

3.1.1 Recognition and measurement

Property, plant and equipment held for use in the supply of services or for administrative purposes, are stated at cost less accumulated depreciation and impairment losses.

3.1.2 Depreciation

Depreciation, which is calculated on the straight line basis, is provided to write off the cost less the estimated residual value of fixed assets over their estimated useful lives. The Group assesses useful life and residual values of property, plant and equipment each year taking into account past experiences and technological changes. No changes to these useful lives have been considered necessary for all other items of property, plant and equipment. Management has set residual values for all classes of property, plant and equipment as zero. Land is not depreciated. The rates that were applied per annum are as follows:

Furniture, fixtures and fittings	10%
Office equipment	25%
Computer equipment	33.33%
Motor vehicles-New	20%
Motor vehicles - pre used	33.3%
Buildings	2.5%
Plant and machinery	10%

3.1.3 Revaluation of Property, Plant and Equipment

Revaluations are performed with sufficient regularity such that the carrying amounts do not differ materially from those that would be determined using fair values at the end of the reporting period.

Any revaluation increase arising on the revaluation of property, plant and equipment is recognized in other comprehensive income, except to the extent that it reverses a revaluation decrease for the same asset previously recognized in profit or loss, in which case the increase is credited to profit or loss to the extent of the decrease previously expensed.

3.1.4 Investment property

Investment property is property held either to earn

rental income or for capital appreciation or for both, but not for sale in the ordinary course of business, use in the production or supply of goods or services or for administrative purposes.

Investment property is initially measured at cost. Cost includes expenditure that is directly attributable to the acquisition of the investment property. The cost of self-constructed investment property includes the cost of materials and direct labour, any other costs directly attributable to bringing the investment property to a working condition for their intended use and capitalized borrowing costs.

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

3.2 Grants and donations

Grants related to assets, including non-monetary grants at fair value, are presented in the statement of financial position as deferred income under non-current liabilities and are recognized as income on a systematic and rational basis over the useful life of the asset.

Revenue grants are recognised as income in the year in which they are received and are credited to the statement of comprehensive income.
Donations are recognised as deferred income when used to purchase assets and are amortised over the economic useful life of the assets.

3.3 Taxation

Income tax expenses represent the sum of the tax currently payable and deferred tax. The currently payable tax is based on taxable profit for the year. Taxable profit differs from profit as reported in the statement of comprehensive income because it excludes items of income or expense that are taxable or deductible in other years and it further excludes items that are never taxable or deductible. The Group's liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the statement of financial position date.

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

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

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

Current and deferred income tax

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

Deferred tax liabilities are recognised for all taxable temporary differences. Deferred tax assets are recognised for all deductible temporary differences and carrying forward of unused tax losses, to the extent that it is probable that taxable profit will be

available against which the deductible temporary differences, and the carry forward of unused tax losses can be utilized.

The Authority is exempted from paying tax.

3.4 Financial Instruments

Financial instruments are contracts that give rise to financial assets or financial liabilities. Financial assets and financial liabilities are recognized on the Group's statement of financial position when the Group becomes a party to the contractual provisions of the instrument. These instruments are generally carried at their estimated carrying values.

Non-derivative financial instruments carried in the statement of financial position comprise: cash and cash equivalents, trade and other receivables, trade and other payables. These instruments are recognized initially at fair value plus any directly attributable transaction costs.

3.4.1 Financial assets

3.4.1.1 Cash and cash equivalents

Cash and cash equivalents comprise cash balances and call deposits (funds on placement) with maturities of three months or less from acquisition date that are subject to insignificant risk of changes in fair value, and are used by the Group in the management of its short - term commitments.

3.4.1.2 Trade and other receivables

Trade and other receivables are measured at their cost less impairment losses. A provision for impairment of trade receivables is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of receivables. Significant financial difficulties of the debtor, probability that the debtor will enter bankruptcy or financial reorganization and default or delinquency in payments are considered indicators that the trade receivables are impaired. When a trade receivable is uncollectible, it is written off against the allowance for trade receivables. Subsequent recoveries of amounts previously written off are credited against the trade receivables impairment provision in profit or loss.

3.4.1.3 Impairment

A financial asset not classified at fair value through profit or loss is measured at each reporting date to determine whether there is objective evidence that it is impaired. A financial asset is impaired if there is objective evidence of impairment as a result of one or more events that occurred after the initial recognition of the asset, and that loss events had an impact on the estimated future cash flows of that asset that can be estimated reliably.

Objective evidence that financial assets are impaired includes default or delinquency by the debtor, restructuring of an amount due to the Group on terms that the Group would not consider otherwise, indications that a debtor will enter bankruptcy, changes in the payment status, and disappearance of an active market for a security.

3.4.1.4 Treasury Bill

Financial assets represent treasury bills held at Standard Chartered Bank. These are non-derivative assets with fixed or determinable payments and fixed maturities. Investments in financial assets will be derecognised once the contractual rights to receive the cash flows deriving from such investments have expired.

3.4.2 Financial liabilities

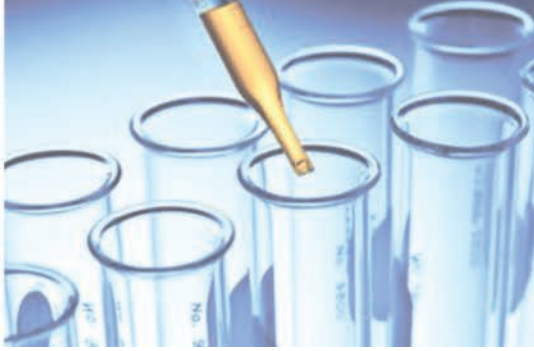
3.4.2.1 Liabilities and provisions

Liabilities payable after one year from the reporting date are treated as non-current liabilities in the statement of financial position. Provisions are recognized when the Group has a present legal or constructive obligation as a result of past events and a reliable estimate to the amount of such obligation can be made. Obligations payable at the demand of the creditor or within one year of the reporting date are treated as current liabilities in the statement of financial position.

3.5. Revenue recognition.

Medicines and laboratory services income is realized after services are or have been rendered. Interest income is accrued over the period in which it is earned based on the underlying agreements. Other income is recognized in accordance with the underlying transactions and events. 30% of the registration income is allocated to samples registration.





Provided the amount of revenue can be measured reliably and it is probable that the Group will receive any consideration, revenue for services is recognized in the period in which they are rendered.

3.6 Employment benefits Defined contribution plan

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

4. Property, plant and equipment

	Land and Buildings	Plant and Machinery	Motor Vehicles	Computer Equipment	Office Equipment	Furniture and Fittings	Total 2015	Total 2014
	US$	US$	US$	US$	US$	US$	US$	US$
Opening carrying amount	**1,547,083**	**930,414**	**281,110**	**115,107**	**17,613**	**95,155**	**2,986,482**	**2,872,772**
Gross carrying amount	1,816,058	1,703,608	621,541	262,879	64,357	149,502	4,617,945	4,135,082
Accumulated depreciation	(268,975)	(773,194)	(340,431)	(147,772)	(46,744)	(54,347)	(1,631,463)	(1,262,310)
Additions at cost	-	509	78,587	25,284	14,349	15,416	134,145	194,805
Donations	-	-	-	1,290	-	-	1,290	339,679
Disposals carrying amount	**-**	**(4,660)**	**(4,924)**	**(4,016)**	**(495)**	**(553)**	**(14,648)**	**(17,848)**
Disposals at cost	-	(15,750)	(27,291)	(6,453)	(495)	(1,523)	(51,512)	(51,621)
Accumulated depreciation on disposal	-	11,090	22,367	2,437	-	970	36,864	33,773
Depreciation for the year	(45,401)	(170,394)	(133,091)	(46,826)	(9,789)	(15,724)	(421,225)	(402,926)
Closing carrying amount	**1,501,682**	**755,869**	**221,682**	**90,839**	**21,678**	**94,294**	**2,686,044**	**2,986,482**
Gross carrying amount	1,816,058	1,688,367	672,837	283,000	78,211	163,395	4,701,868	4,617,945
Accumulated depreciation	(314,376)	(932,498)	(451,155)	(192,161)	(56,533)	(69,101)	(2,015,824)	(1,631,463)

		MCAZ GROUP		AUTHORITY	
		2015 US$	2014 US$	2015 US$	2014 US$
5	**Investment property**				
	Opening amount carrying amount	1,838,500	2,829,750	1,338,500	2,229,750
	Fair value adjustment	-	(391,250)	-	(291,250)
	Prior year adjustment	-	(600,000)	-	(600,000)
	Closing carrying amount	1,838,500	1,838,500	1,338,500	1,338,500
6	**Investment in subsidiary**				
	Percentage Discount Pvt Ltd	-	-	218,595	209,573
	Prior year adjustment	-	-	-	9,022
	Closing carrying amount	-	-	218,595	218,595
7	**Inventories**				
	Fuel	11,431	28,428	11,431	28,428
	Provisions	1,639	4,058	1,639	4,058
	Stationery consumables	11,324	4,935	11,324	4,935
		24,394	37,421	24,394	37,421
8	**Trade and other receivables**				
	Trade receivables	502,181	304,969	487,605	297,343
	Allowance for credit loss	(204,263)	(204,263)	(204,263)	(204,263)
	Rentals	28,708	30,707	28,708	30,707
	Staff receivables	92,093	57,884	92,093	57,884
	Related party receivables	-	-	36,007	26,508
	Sundry receivables	52,445	114,983	52,445	114,983
		471,164	304,280	492,595	323,162
9	**Cash and cash equivalents**				
	Bank	219,664	443,363	186,392	435,220
	Funds on placement	258,552	124,905	258,552	124,906
		478,216	568,268	444,944	560,126
10	**Deferred income**				
	Opening carrying amount	605,274	380,749	605,274	380,749
	Additions of donated equipment	1,290	339,679	1,290	339,679
	Amortisation charge for the year	(110,516)	(115,154)	(110,516)	(115,154)
	Closing carrying amount	496,048	605,274	496,048	605,274

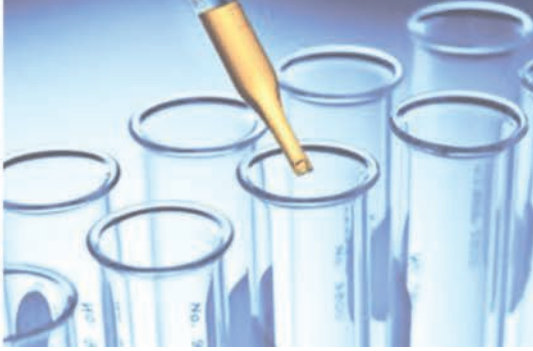
		MCAZ GROUP		AUTHORITY	
		2015 US$	2014 US$	2015 US$	2014 US$
11	**Trade and other payables**				
	Audit fees	19,890	29,630	19,890	29,630
	Trade payables	32,418	-	32,418	-
	Related party payables	-	-	3,600	5,227
	Sundry payables	176,178	337,767	172,578	337,767
	Unallocated income	23,988	28,360	23,988	28,360
		252,474	**395,757**	**252,474**	400,984
12	**Medicines control income**				
	Amendment fees	91,201	67,573	91,201	67,573
	Clinical trials	41,850	31,500	41,850	31,500
	Dangerous drug license	11,045	14,156	11,045	14,156
	Drug registration and forensic examination	14,515	15,100	14,515	15,100
	Import and export licenses	277,147	288,724	277,147	288,724
	Inspection	368,786	238,395	368,786	238,395
	Persons and premises licenses	171,095	175,693	171,095	175,693
	Registration fees	581,311	874,149	581,311	874,149
	Renewal of licenses	328,302	337,310	328,302	337,310
	Retention fees	672,108	642,296	672,108	642,296
	Sales representatives and wholesale dealers	179,210	152,320	179,210	152,320
	Training medicines	2,500	-	2,500	-
	Unregistered medicines	229,488	171,893	229,488	171,893
	Veterinary permits	45,220	43,870	45,220	43,870
		3,013,778	**3,052,979**	**3,013,778**	**3,052,979**
13	**Laboratory services Income**				
	Condom testing	59,500	83,990	59,500	83,990
	Complementary medicines	4,895	200	4,895	200
	Laboratory	-	1,756	-	1,756
	Training medical devices	-	1,133	-	1,133
	Glove testing	14,000	4,450	14,000	4,450
	Medical devices-registration	550	168	550	168
	Samples-external clients	407,439	112,955	407,439	112,955
		486,384	**204,652**	**486,384**	**204,652**

		MCAZ GROUP		AUTHORITY	
		2015 US$	2014 US$	2015 US$	2014 US$
14	Other income				
	Amortisation for the year	110,517	115,154	110,516	115,154
	Donations received	170,060	362,344	170,061	362,344
	Interest earned	25,278	35,998	25,278	35,490
	Rentals	193,063	153,912	153,463	128,652
	Sundry income	129,364	8,508	138,864	12,108
	Profit on disposal of property, plant and equipment	17,159	-	17,159	-
		645,441	**675,916**	**615,341**	**653,748**
15	Other expenses				
	Employment costs				
	Salaries and wages	2,130,738	1,820,299	2,130,738	1,820,299
	Pension and medical aid	132,384	234,526	132,384	234,526
	Staff training expenses	23,745	17,859	23,745	17,859
	Staff welfare	15,623	24,517	15,623	24,517
		2,302,490	**2,097,201**	**2,302,490**	**2,097,201**
16	Related party transactions				
	The remuneration of the Board members and other key management personnel during the financial year was as follows:				
16.1	Board members benefits	31,829	13,150	31,829	13,150
	Board members fees	55,384	74,016	51,225	70,283
		87,213	**87,166**	**83,054**	**83,433**
16.2	Key management staff				
	Remuneration of key management staff of the commission comprise of annual basic salary annual bonus, social security contributions, pension and medical aid contributions				
	Director general benefits	7,200	7,200	7,200	7,200
	Director general salary	66,504	64,896	66,504	64,896
		73,704	**72,096**	**73,704**	**72,096**

		MCAZ GROUP		AUTHORITY	
		2015 US$	2014 US$	2015 US$	2014 US$
17	Administration expenses				
	Audit fees	11,104	18,088	7,090	17,010
	Board fees	87,213	87,166	83,054	83,433
	Bank charges	27,650	24,008	27,171	23,187
	Communications	47,955	57,272	47,955	57,272
	Consumables	42,191	29,467	42,191	29,467
	Meeting expenses	31,312	27,280	31,312	27,280
	Depreciation expenses	421,225	402,926	421,225	402,926
	Fair value adjustment on investment property	-	391,250	-	291,250
	Fines	-	14,531	-	14,531
	General administration	54,053	48,246	54,053	48,246
	Inspections	222,744	157,141	222,744	157,141
	General expenses	3,600	148,106	-	145,580
	IT expenses	15,795	15,601	15,795	15,601
	Legal and professional fees	106,854	56,236	106,854	55,193
	Loss on disposal of property, plant and equipment	-	668	-	668
	Printing and stationery	61,639	62,452	61,639	62,452
	Increase in allowance for credit losses	-	204,263	-	204,263
	Increase for leave pay provision	24,332	22,665	24,332	22,665
	Public relations	39,618	24,436	39,618	24,436
	Quality assurance costs	13,268	599	13,268	599
	Rates, electricity and water	26,803	23,106	26,803	21,477
	Repairs and maintenance	141,563	157,494	141,068	146,329
	Security and insurance costs	21,796	41,471	21,796	41,471
	Strategic planning	143,024	128,600	143,024	128,600
	Subscriptions	11,904	25,024	11,904	25,024
	Travelling and subsistence	39,186	53,311	39,186	53,311
	Vehicle running costs	197,267	140,692	197,267	140,692
		1,792,096	**2,362,099**	**1,779,349**	**2,240,104**

		AUTHORITY 2015 US$	2014 US$
18	**Prior period error**		
	Prior period error		
	Revaluation reserve, retained earnings and investment property were overstated in error. A prior year adjustment has been made to correct the position.		
	Impact on the statement of financial position		
	Decrease in retained earnings	-	333,724
	Decrease in revaluation reserve	-	381,404
	Decrease in equity	-	**715,128**
	Impact on retained earnings		
	Elimination of depreciation due to change in policy	-	198,750
	Adjusting investment property to align it with its valuation	-	10,824
	Adjusting retained Income previously overstated	-	124,150
	Decrease in retained earnings	-	**333,724**
	Impact on revaluation reserve		
	Adjusting revaluation reserve incorrectly captured	-	381,404
	Decrease in revaluation reserve	-	**381,404**





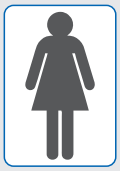
HUMAN CAPITAL

The Authority continued with the implementation of a number of policies to ensure high ethical standards, employee welfare and satisfaction. These policies are highlighted below:

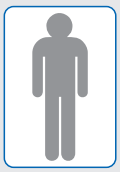
1. Code of Ethics policy to promote high ethical standards as well as to inculcate a sense of commitment, responsibility and dependability in the workplace.
2. Anti-corruption policy aimed at creating an anti-corruption culture and the prompt detection of corruption which cannot be prevented.
3. Group Funeral Scheme and Funeral Allowance policy to allow for the decent burial of Authority employees and their immediate families in times of bereavement.
4. Employee Wellness policy to empower employees to prevent the onset of disease and the promotion of healthy lifestyles as well as provide guidelines to employees at all levels on key wellness solutions in the workplace.

This has significantly improved employee engagement and retention as they feel that the Authority is concerned about the welfare of its employees. This is evidenced by a low labour turnover of an average of 2.98% in the reporting period. The total staff establishment during the reporting period was 102 and as of 31st December 2015, there were six vacant positions. Table 1 shows the Authority's staff establishment.

96 Total Staff



48 Females



48 Males

Table 1: *The Authority's staff establishment as at 31st December 2015*

Division / Unit	Gender		Total staff	Approved Positions
	Male	Female		
Director General's Office	0	2	2	2
Human Resources	1	1	2	2
Quality Systems	0	3	3	3
Internal Audit	1	0	1	1
Microbiology & Medical Devices	4	5	9	10
Evaluations & Registration	9	9	18	18
Licensing & Enforcement	4	8	12	14
Pharmacovigilance & Clinical Trials	3	3	6	6
Chemistry Laboratory	7	6	13	13
Finance	3	4	7	7
Administration	14	5	19	20
ICT	2	0	2	2
Legal & Corporate Affairs	0	2	2	4
Total	**48**	**48**	**96**	**102**

In addition to the approved positions, the Authority had four project funded positions (three in Pharmacovigilance and Clinical Trials (PVCT) Division and one in Licensing and Enforcement Division) and eight graduate interns/ pre-registration pharmacists.

Evaluations and Registrations

Human Medicines

The Division continues to ensure that products intended for marketing in Zimbabwe comply with MASCA [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 incorporates 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 The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines. The overall median timeline to registration in 2015 was 845 days (IQR 451 - 986 days). This is inclusive of the manufacturers' time to respond to queries.

Highlights

257
Applications for registration of Human Medicines

183 Registered

37 Refused registrations

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.*

The register of approved human medicines is available on the MCAZ website and is updated on a quarterly basis.

The Authority continued to participate in the ZAZIBONA collaborative registration process. Four assessors meetings were held in 2015 and 54 new products were assessed and are at various stages of completion.

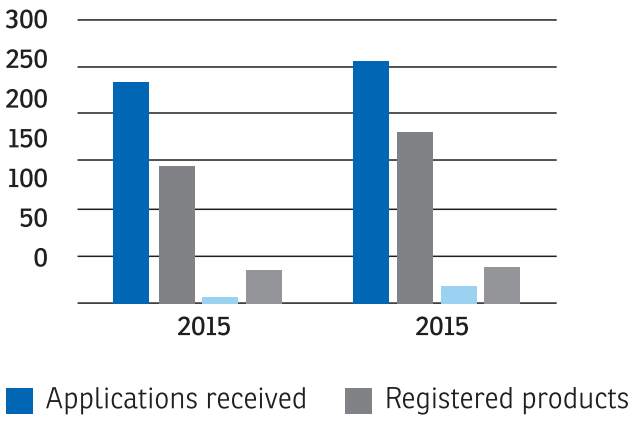


Figure 1: Comparison Of Human Medicines Processed In 2014 And 2015

Veterinary Products

A similar process to that of human medicines is carried out for the registration of veterinary medicines in line with MASCA [15:03] and MCAZ Guidelines. The process incorporates principles from the SADC Harmonisation Technical Requirements for Registration of Veterinary Medicines Guidelines, the World Organisation for Animal Health-Organisation internationale de Epizooties (OiE) and the International Conference on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products in areas where the common guideline does not fully address issues unique to veterinary medicines such as residue depletion studies and withdrawal periods.

In addition to the above standard of registration requirements, applicants wishing to register acaricides (dip chemicals) for the control of ticks have to submit applications for conducting local (in-country) dipping trials co-approved by MCAZ and the Department of Veterinary Services. This ensures the choice of the appropriate dipping trial sites, one in the highveld and another in the lowveld, and confirms the presence of the important tick species in significant numbers to guarantee validity of the acaricidal efficacy of the dip, as well as monitor correct use of the product and adherence to animal welfare standards prescribed by the Animal Health Act [19:02].

Highlights

11

Applications for registration of Veterinary Medicines in 2015

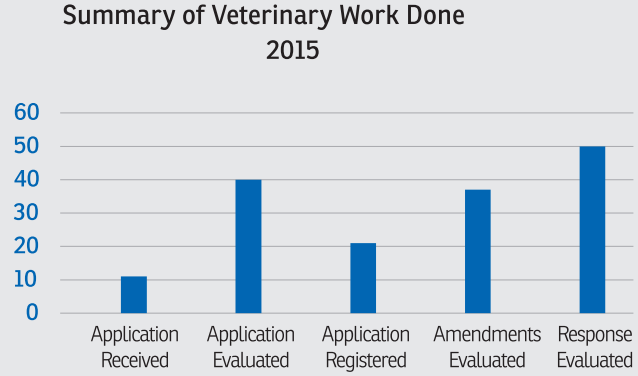


Figure 2: Summary of Veterinary Work done 2015

Figure 2 above shows a summary of the work done in 2015. The number of applications received was 11. This was a significant drop from the 33 applications received in 2014. However, despite this decrease in product submissions, 20 products were registered, compared to 14 products in 2014. Of the applications registered in 2015, 4 were vaccines, 6 antibiotics, 1 acaricide (dip), 1 vitamin supplement, 1 anaesthetic drug, 1 babesiocide and 6 anthelminthics (dewormers).

A consultative meeting to revise the Dipping Trial Guidelines published in 2003 was held on the 19th of February 2015 at the Rainbow Towers Hotel. It was attended by stakeholders from the Animal Health Industry Committee (AHIC) of Zimbabwe and academia from the University of Zimbabwe and Harare Institute of Technology. The review of the guidelines resulted in the final draft of the dipping trial guidelines which was approved by the Director General and published on the MCAZ website.

Another consultative meeting for the finalization of the CTD Guidelines for the Registration of Veterinary Medicines was held at Bronte Garden Hotel on Friday 8th May 2015. The meeting was attended by members from the AHIC of Zimbabwe, South African Animal Health Industry and medicines regulatory agency representatives from Namibia. Previously, the registration of veterinary medicines was based on the CTD Guidelines for registration of human medicines with subjective application of the principles. The common deficiencies noted in applications were also discussed at the consultative meeting. The guideline was approved in December 2015 and is available on the MCAZ website.

Complementary and Herbal Medicinal Products

These medicines include herbal, nutraceutical, homeopathic and anthroposophic medicinal products. The Complementary Medicines Regulations were approved in September 2015 by the Minister of Health & Child Care (MoHCC). No new applications were received for the remainder of the year after the publication of the regulations.

Submissions of Complementary Medicine Applications to determine registerability	**228** (2014)		**582** (2015)

Highlights

- **41** Number of complementary medicines found either making medicinal claims or containing medicinal ingredients, thus requiring thorough evaluation under the normal registration procedures for allopathic medicines.
- **18** Number of complementary medicines deemed not registerable and were given clearance to be marketed as complementary medicines.
- **5** Number of complementary medicines that were either not a complementary medicine or additional information was requested on the application

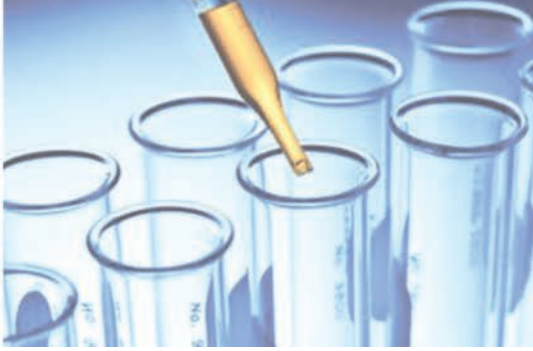
The above statistics are for products submitted in 2015 as complementary medicines and which were assessed using the exemption-based system of products that did not contain allopathic medicinal ingredients nor make medicinal claims. Towards, the end of the first half of 2015, there was a decline and then gradual halt in assessments of complementary medicines because of the imminent publication of the complementary medicine regulations.

Meetings with Customers

The Evaluation and Registration Division holds meetings with applicants to clarify content and procedural issues (Pre-submission Advice, Technical Advice and Clarification Meetings) in the interest of efficiency and transparency of the authorisation procedures. The Evaluations and Registration (EVR) Division and Management review the outcome of the meetings and any lessons learnt are applied to enhance continuous improvement and customer focus.

In 2015, a total of ninety-one (91) company meetings were held with applicants compared to ninety-five (95) meetings held in the previous year.





LICENSING AND ENFORCEMENT

Licensing of premises

Companies that manufacture, distribute (import, export or wholesale) or dispense medicinal products in Zimbabwe must have a premises licence or permit. MCAZ issues these licences and permits, on the basis of a successful pre-approval inspection.

Licensing of persons

All health professionals who dispense medicines are required by law to be licensed. The Authority licences pharmacists, pharmacy technicians, medical doctors, veterinary surgeons and nurses to dispense medicines at the different types of licensed premises, upon submission of satisfactory applications.

Authorisations for Importation of Unregistered Medicines

The provisions under Section 75 of the Act allow MCAZ to authorise the importation of unregistered medicines, if such medicines are considered to be the best standard of care by the attending medical practitioner. The medicines must be essential for the treatment of specific patients. On submission of an application, MCAZ will issue medical practitioners and/or institutions an authorisation letter for the importation and use of small quantities of the medicinal products that are not registered in Zimbabwe. Each authorisation is for a named patient or institution.

Screening and Authorisation of Donations

A number of institutions, particularly mission hospitals, receive donations from program partners. MCAZ processes applications for donations, assessing the suitability of the medicines and the ability of the intended recipient to manage the medicines. The donations are screened in accordance with the Guidelines for Donations published by the MoHCC.

Control of the Import and Export of Narcotics Zimbabwe is a signatory to the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. MCAZ is tasked by the Permanent Secretary for Health & Child Care to administer the Dangerous Drugs Act (Chapter 15:02). MCAZ is also responsible for the monitoring and control of psychotropic substances. Controls are effected through the provisions in the Dangerous Drugs Act (Chapter 15:02), and the Dangerous Drugs Regulations, 1975 (RGN 1111 of 1975) as well as the Medicines & Allied Substances Control Act (Chapter 15:03). MCAZ therefore issues import, export and possession licences to companies who manufacture, procure or possess controlled substances. MCAZ also issues permits as a means of controlling the import and export of precursor substances. Precursors are substances that, although having legitimate uses, can be used in the manufacture of illicit drug substances.

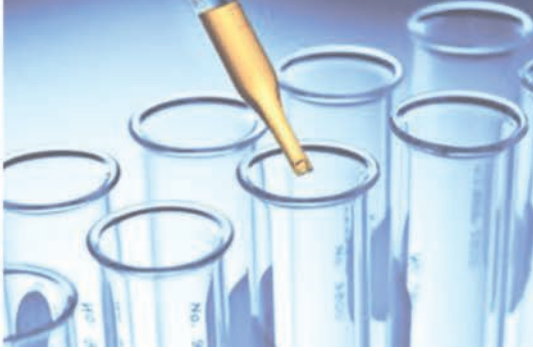
Inspections

MCAZ carries out inspections as prerequisites for issuing or maintaining a premises licence. Adherence to current Good Manufacturing Practices (cGMPs) is assessed for the manufacturers of pharmaceutical products whilst Good Distribution Practices are assessed for wholesalers. Pharmacies, dispensing medical practices or veterinary practices, and health institutions are also inspected for good dispensing and storage practices in line with the requirements of the legislation. MCAZ aims to inspect all premises at least once every two years.

Import and Export Control

The import and export of medicines is regulated by MCAZ through Statutory Instrument 57 of 2008. MCAZ issues authorized dealers in medicines with a permit for importing or exporting each and every consignment of registered medicinal products through designated ports.





Total Licences and permits for manufacturers, distributors and pharmacies 1,155

19.8% increase in licenced premises

- Pharmacy licences 616
- Wholesale dealer's permits 78
- Industrial clinics licences 193
- Veterinary medicines general dealers' permits 203
- Manufacturer's licence 10
- Medical practitioner's dispensing licences 55

Total Persons Licences 1,281

22% increase in persons licences

- Pharmacists 616
- Pharmacy Technicians 49
- Dispensing Medical Practitioners & Veterinary Surgeons 144
- Nurses 371
- Sales Representative Permits 101

- The number of section 75 applications processed in 2015 for human use came to a total of 5279, which was an increase of 5.4% from those processed in 2014. This increase is attributed to the introduction of a fee for medicines that do not comply with labelling requirements. Further, there has been an increase in the number of new molecules for individual prescription application not on the bulk importation list.

- One thousand and sixteen (1016) of the section 75 authorisations issued for human medicinal products came from institutions as well as wholesalers importing in bulk. Some of these were for registered products with non-complaint labelling on importation. Four thousand two hundred and sixty-three (4263) applications were for individual prescriptions.

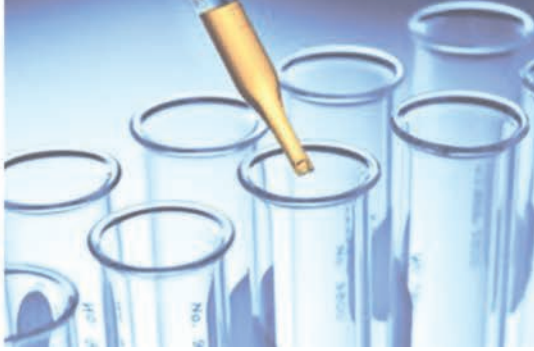
129 | Number of Approved donations for entry into Zimbabwe

109 | Number of licences to import narcotics and psychotropic substances

18 | Number of licences to possess, acquire and administer narcotics, including game capture licences

187 | Number of permits for the importation of precursor substances were issued.





694 inspections of licensed premises were carried out by the MCAZ Inspectorate in 2015 compared to 616 in 2014.

In 2015, 119 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 131 conducted using the same support in 2014

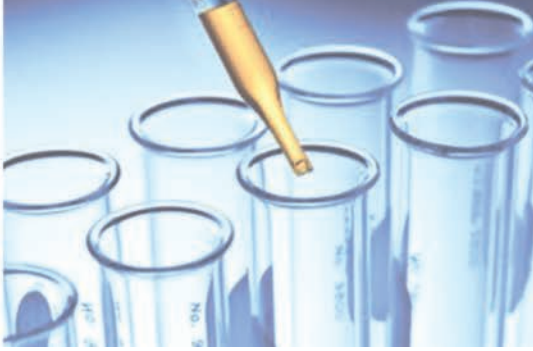
Inspectorate carried out 74 special investigational inspections in 2015 compared to 20 in 2015.

1441 Import permits

69 Export permits

- In order to increase effectiveness with respect to port monitoring, a regulatory officer was hired to monitor the Beitbridge port. However, the officer left the organisation before deployment to Beitbridge Port in the third quarter of 2015. A new officer will be recruited.
- Harare International Airport continued to be monitored daily from Monday to Friday and all consignments containing medicines entering through this port were physically verified.
- MCAZ continued to work in collaboration with ZIMRA and Port Health Officials in the clearing of consignments containing medicines at the ports of entry.





Pharmacovigilance and Clinical Trials

The quality, safety and efficacy of medicinal products and medical devices are constantly monitored by MCAZ, even after they have been launched on the market. The Pharmacovigilance and Clinical Trials Division is responsible for pharmacovigilance, post marketing surveillance, regulation of clinical trials of medicines, processing applications for amendments or variation of registered medicines, application for re-instatements of cancelled products, processing product defects and recalls and annual retentions of registered medicines.

Pharmacovigilance

Reports on adverse drug reactions are evaluated and recorded in the WHO Uppsala Monitoring Centre database called Vigibase. The reporting professionals receive appropriate feedback. In addition, reports of adverse drug reactions from within Zimbabwe reach MCAZ through the pharmaceutical companies. We acknowledge with thanks the funding received from HDF, UNICEF and Global Fund to expand and strengthen pharmacovigilance in Zimbabwe that includes identification of risks associated with vaccines and essential medicines and communication of the information in a way that improves therapeutics and patient safety.

Targeted Spontaneous Reporting

As was reported in the 2014 report, MCAZ in collaboration with the MoHCC conducted a pilot phase of Targeted Spontaneous Reporting (TSR) of ARVs and Anti-TBs in public and selected private health institutions from October 2012 to September 2013. The TSR pilot phase demonstrated a significant increase in ADR reporting and was considered a relatively feasible, cost effective method, hence TSR was scaled up to the main phase program (October 2013 to December 2015). Staff at the MCAZ, in collaboration with the MoHCC (National AIDs and TB programme and Directorate of Pharmacy Services) are responsible for coordinating the program, training of sites, and collection of reports and data analysis. Meetings were held with key partners before implementation of the program to create awareness of TSR of ARVs and to gain their understanding, support and participation in program implementation, monitoring and evaluation. In 2015 MCAZ-PVCT Division conducted targeted spontaneous reporting trainings in Matabeleland, Harare and Mashonaland West Provinces. The main objectives of the training sessions were centred on explaining the need for and role of pharmacovigilance, feedback on the TSR program, quality of ADR reports and completeness score. Emphasis was also given on the need for participation by health professionals in the current TSR program. The training sessions conducted were as shown in the table below.

Date Training Conducted	Site / Province	Number of Health Professionals Trained
7 December 2015	Mashonaland West	26
8 December 2015	Harare	30
10 December 2015	Matabeleland	18
Total		**74**

Table 2: *TSR Trainings Conducted in 2015*

Strengthening National Surveillance of Adverse Events Following Immunisation

The MCAZ acknowledges with thanks the AEFI reports received from the Zimbabwe Expanded Programme on Immunization (ZEPI) and trainings of ZEPI staff countrywide over the years. Training on Advanced AEFI causality assessment by the WHO was conducted in November 2015, MCAZ staff, ZEPI staff and National AEFI committee members were trained. The AEFI Reporting and investigations forms were revised by MCAZ and ZEPI with the help of WHO experts. In 2015 the AEFI Surveillance guidelines were revised and were aligned with the WHO Global manual on surveillance of AEFI and the current standards. There was in increase in the number of AEFI reported cases in 2015 (77) as compared to 2014 (22). This could have been attributed to the sensitization programme done for the Measles Rubella Vaccine which was launched in 2015 and the trainings conducted. 81% of the AEFIs reports received in 2015 were non-serious, 11 % were serious and 8 % of the reports were fatal.

Highlights

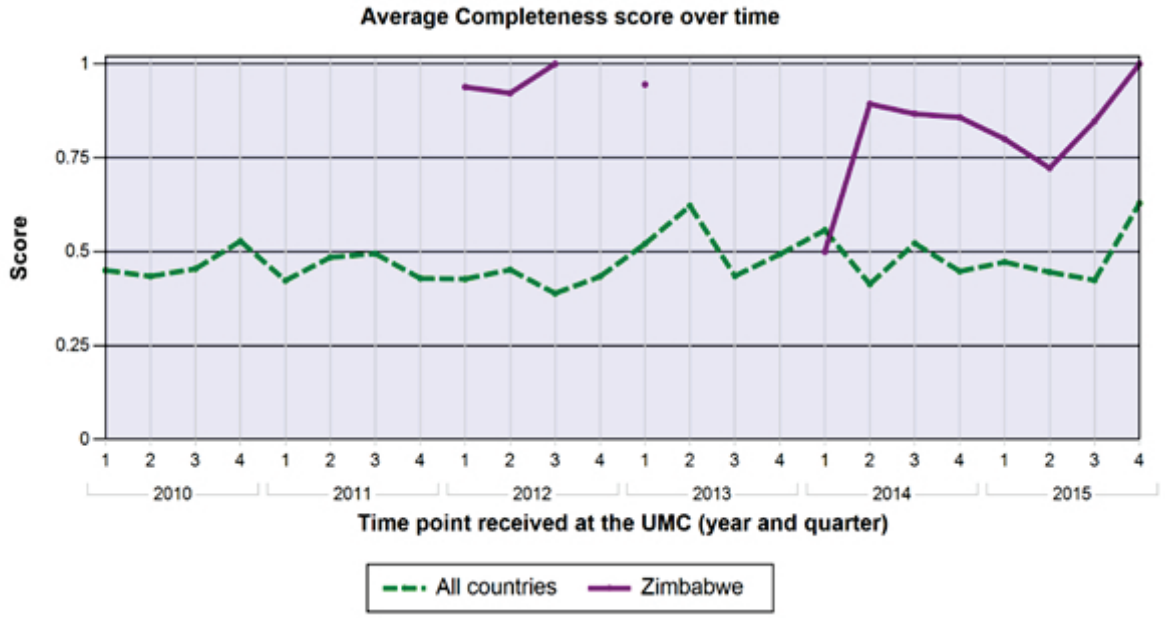
Pharmacovigilance

626 Total Individual Case Safety Reports Received in 2015

Adverse events following immunizations (AEFI) **77**		Targeted Spontaneous reports (TSR) **315**
Serious adverse events (SAEs) from Authorised Clinical Trials **207**		SAE reports from Pharmaceutical Industry **27**

The reports received were also uploaded onto the WHO Vigiflow database which is also used as the in-house drug safety database. Zimbabwe through the MCAZ is a participating member to the WHO International Drug Safety Monitoring Programme.

The MCAZ received feedback from the WHO-Uppsala Monitoring Centre for January to December 2015 reports and Zimbabwe maintained its position for the highest quality of ICSRs submitted to the VigiFlow and VigiBase database, as illustrated in the graph below. This is a great achievement and is attributed to the TSR trainings conducted over the years. Draft manuscripts for the effectiveness of TSR methodology and the Zimbabwe VigiGrade completeness score are being drafted for publication in the Drug Safety Journal.



Source: The Uppsala Monitoring Centre, VigiGrade Completeness Score Report for Zimbabwe, 2015

Figure 3: Average Completeness Score Over Time

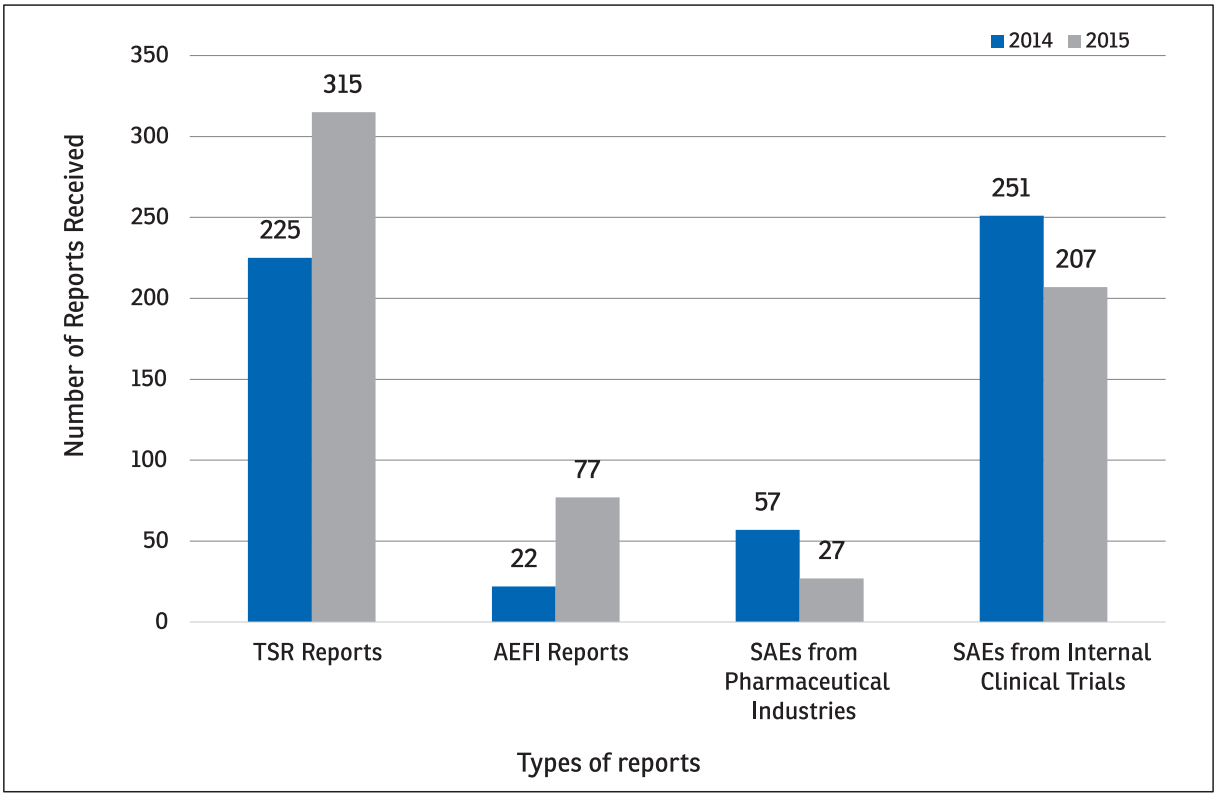


Figure 4: *Comparative analysis of Individual Case Safety Reports for 2014 and 2015*

The total number of safety reports received in 2015 (626) increased as compared to 2014 (595). There was an increase in the number of TSR and AEFI reports in 2015 as compared to 2014 and this could be attributed to the impact of TSR trainings which were conducted by the MCAZ-PVCT division. As illustrated in the graph above the number of SAEs from clinical trials and pharmaceutical industry decreased in 2015 as compared to 2014.

Electronic ADR reporting system

MCAZ in collaboration with the Uppsala Monitoring Centre set out to introduce an electronic ADR reporting system. An e-ADR reporting system is targeted to be launched by June 2016.

Post marketing surveillance activities

Guidelines for the notification of a medicinal product problem/defect and recall procedure were revised in line with the current international trends and local requirements. There was an increase in product defects reports received in 2015 (5) as compared to 2014 were 2 product defect reports were received. All the 5 product defects reports received in 2015 were processed as shown in the table below.

Name of Product & Batch No.	Manufacturer	Nature of defect or Problem	Recommendation(s) /Actions Taken
Amoxicillin 250mg Capsules (Imox 250) Batch PU152009	IPCA Laboratories, India	Capsules were stuck together as a lump, dry, brittle, and deformed	Affected batches were quarantined, samples were sent to the MCAZ laboratory for analysis. The manufacturer was required to conduct investigations of the root causes of the product defect. The root cause analysis was still ongoing and expected to be submitted to the Authority once completed.
Fentanyl 100mcg Patches (Fentavera) Batch P0051AB0AE	Acino AG, Germany	Label of the patches indicated Active Ingredient as 20mg instead of 20.4mg	Manufacturer recalled the batch and was granted permission to destroy the recalled batch. This product is not registered and it was imported under section 75.

Name of Product & Batch No.	Manufacturer	Nature of defect or Problem	Recommendation(s) /Actions Taken
Metformin 500mg Tablets (Metfin) Batch 0515219	Plus Five Pharmaceuticals	Unpleasant smell emanating from the tablets	MCAZ conducted laboratory analysis. the sample from the reporter failed assay test whilst the manufacturer's retention sample passed. The manufacturer was requested to carry out investigations to ascertain the root cause of the defect. The investigations were still ongoing to determine the root cause of the problem and a product based GMP inspection by MCAZ would also be conducted as part of the investigations.
Tenofovir Disoproxil Fumarate / Lamividune 300mg /300mg (Tenolam) Tablets Batch E140140	Hetero Labs Ltd, India	Wrong packaging, secondary pack (carton) for Tenolam-E 300mg/ 300mg/600mg tablets was used to pack Tenolam 300mg/300mg Tablets	Class II recall was done and affected batches were quarantined.
Hydrocortisone Sodium 100mg Injection (Solu-cortef) Batches L17642 and L17642	Pfizer Laboratories, South Africa	Different presentation of the vial to the registered one.	There were no safety and quality issues as the correct type of primary packaging was used. Quarantined batches were approved to be distributed.

Changes in Category of Distribution for Medicines in Zimbabwe

The PVCT Division is also responsible for review of safety of new and old medicines including category for distribution of medicines. In 2015, the MCAZ re-categorised Epinastine Hydrochloride eye drops as shown in the table below. Letters to the applicants and a circular to this effect were written.

Trade Name	Generic Name	Registration Number	Category for distribution	Reason
Relestat Eye Drops	Epinastine Hydrochloride	2014/19.9/4899	From Prescription Preparation (PP) to Pharmacist Initiated Medicine (PIM)	Similar product registered in the PIM category.

Table 4: *Changes in Categories for Distribution of Medicines*

Post-Registration Amendments and Applications for Re-Instatements

Applications must be made for approval of any variations/amendments to medicinal products registered by MCAZ. These applications are evaluated and approved by the Registration Committee.

2015 Highlights

- In 2015, 542 applications for approval of variations/amendments to registered medicines were submitted. 384 amendments received in 2015 were still under review owing to the submission of inadequate information by applicants and also due to non- payment of amendment fees. 39 applications were considered abandoned due to non-payment of amendment fees. 119 applications were processed.

- A total of 5 applications for re-instatement of registration of cancelled products were received, 4 of which were processed and 1 application was pending.
  There was an increase in the number of amendments to registered medicines as in 2015, 542 amendments were received and in 2014, 346 amendments were received as reported in the 2014 report.

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 products is cancelled and gazetted as such. Notification in writing is required if a medicinal product is no longer to be retained and distributed and the registration of the product will be cancelled.

Highlights

Foreign Products **93%**	**Payment of Retention Fees**	Foreign Products **79%**
Local Products **61%**		Local Products **80%**
HUMAN MEDICINES		VETERINARY MEDICINES
1686 IN 2015 VS. **1356** IN 2014		**323** IN 2015 VS. **303** IN 2014
38 IN 2015 VS. **28** IN 2014	**Cancelled Products**	**11** IN 2015 VS. **4** IN 2014

Regulation of clinical trials of medicines in humans

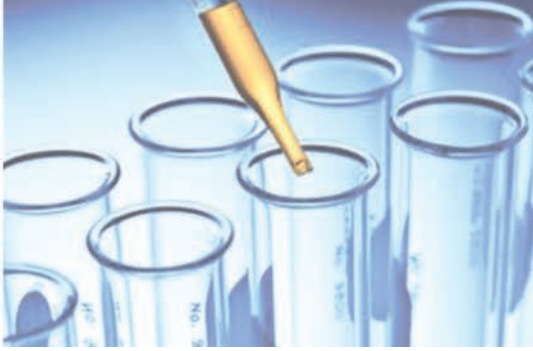
Applications must be made for authorisation of clinical trials of medicines in humans, including applications for amendments to the protocol, serious adverse event (SAEs) reporting, progress reports and good clinical practice (GCP) inspections and applications for importation of investigational products.

Highlights

10 clinical trial applications were received and authorised. A GCP inspection was conducted for the clinical research site which had a high number of serious adverse events to monitor compliance with GCP. Compliance with GCP was also monitored through processing of SAEs, amendments to clinical trials, clarification memos, protocol deviation reports, progress reports and review of data safety monitoring board reports.

78 applications for importation of clinical trial investigational medicines were received in 2015 and authorised.





CHEMISTRY LABORATORY

Both accreditation and WHO prequalification were key to the success of the laboratory. An increase in external samples was observed and many external enquiries were received from various countries in Africa.

The Chemistry Laboratory was a hive of activity in the year 2015 in an effort to increase productivity as well as revenue for purposes of viability. A target of 500 samples was set by the Authority and the laboratory managed to surpass this target by 159 samples.

In view of the regulatory mandate, stepping up of productivity was important in order to enable analysis of all post market surveillance samples collected from the ten provinces in Zimbabwe. The major local projects conducted in 2015 covered were analysis of anti-tuberculosis, anti-malarial and anti-retroviral drugs. Essential medicines were also tested under the Health Development Fund (HDF). This approach was necessary to ensure that good quality products were available on the market. Safety and efficacy issues were also monitored to save the patients from unscrupulous manufacturers. Overall the quality and efficacy of the tested medicines were high and only a few failing products were detected.

As a regional centre of excellence the laboratory managed to collaborate with the Network of official medicines quality control laboratories (NOMCoL Africa) under the USP Technical Assistance program, by hosting teams of laboratory heads and analysts from Zambia, Tanzania, Botswana and Mozambique under technical exchange programs.

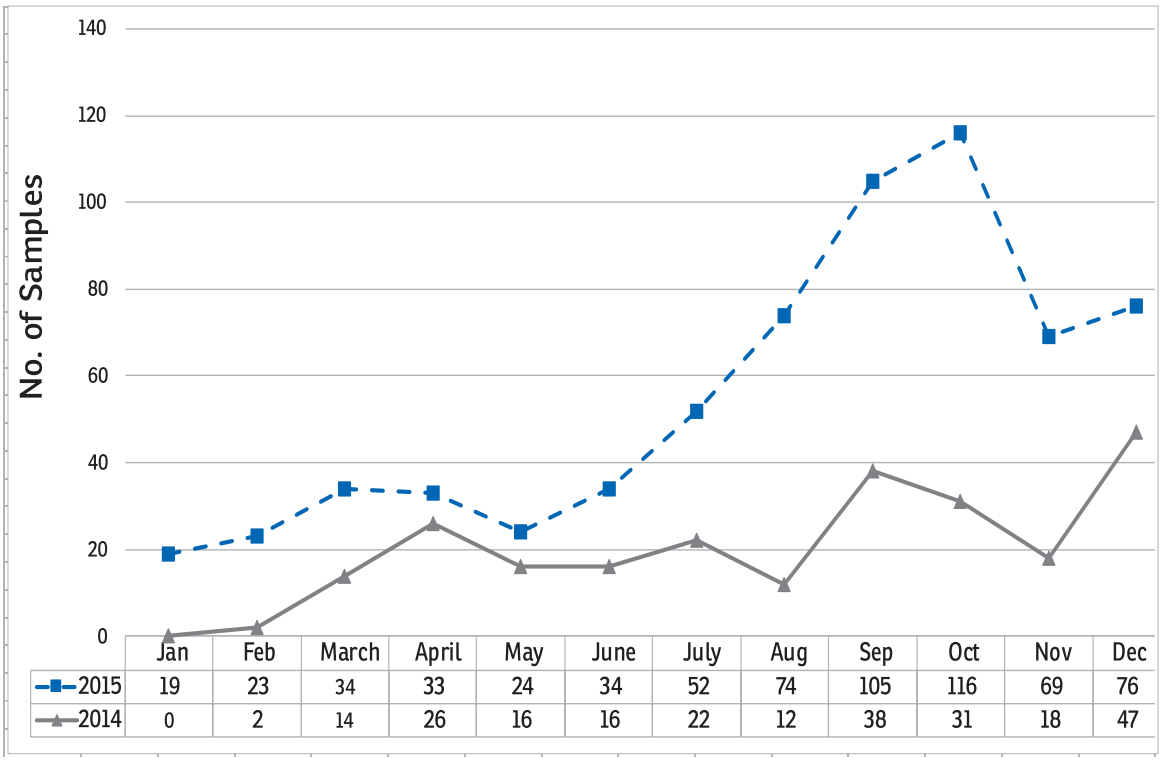
Another achievement was a crossover of accreditation from SANAS to a regional accreditation system, SADCAS in September 2015 after an audit in the month of February.

Inter-laboratory Proficiency Testing

In the year 2015 the Chemistry Laboratory participated in two inter -laboratory proficiency testing schemes and performed satisfactorily.

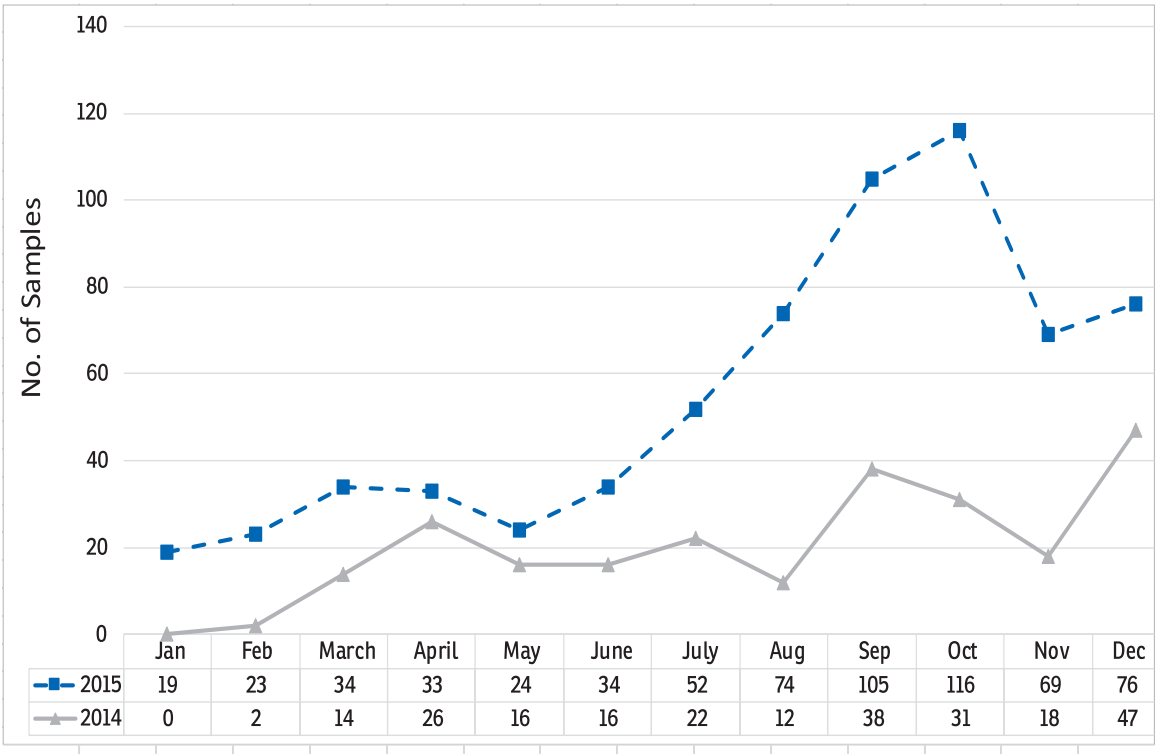
Laboratory Productivity 2015

The productivity of the laboratory increased by 300% in the year 2015. The comparison between 2014 and 2015 is shown in the graphs on the next page:-



	Jan	Feb	March	April	May	June	July	Aug	Sep	Oct	Nov	Dec
2015	19	23	34	33	24	34	52	74	105	116	69	76
2014	0	2	14	26	16	16	22	12	38	31	18	47

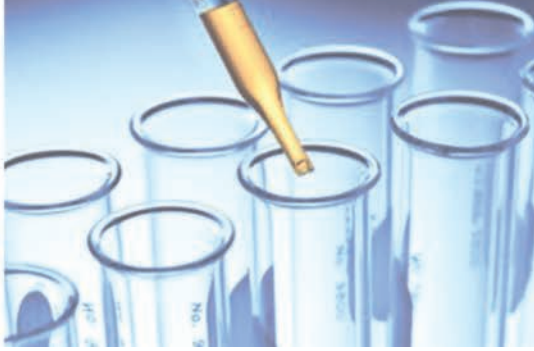
Figure 5. *Graph of a comparison of Number of Samples Analysed in 2014 vs 2015*



	Jan	Feb	March	April	May	June	July	Aug	Sep	Oct	Nov	Dec
2015	19	23	34	33	24	34	52	74	105	116	69	76
2014	0	2	14	26	16	16	22	12	38	31	18	47

Figure 6. *Graph of a comparison of Number of Samples Received in 2014 vs 2015*



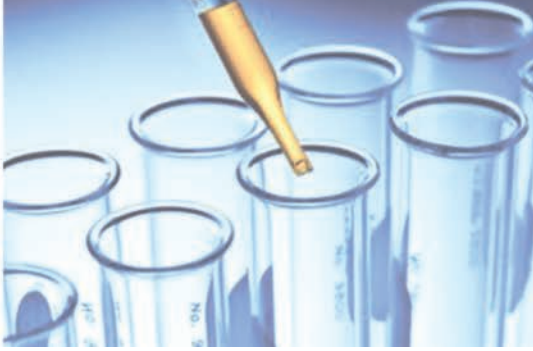


735
Samples Received

659
Samples Analysed

11
Failed samples(1.7%)





Medical Devices And Microbiology Unit

The MCAZ Microbiology Laboratory is responsible for the microbiology laboratory analysis of medicines and allied substance according to the purview of Medicines and Allied Substances Control Act (Chapter 15:08). The laboratory examines sterile and non-sterile pharmaceutical products, complementary medicines, nutraceuticals, dietary supplements and other allied substances for pathogenic and non-pathogenic microorganisms, and assessing potency. Further the laboratory also performs batch/lot release for all vaccines coming into Zimbabwe.

Activities

- The laboratory received one-hundred and eighty-five (185) samples for analysis in 2015. This represented an increase of 42% from the previous year.

- A total of one-hundred and ninety-six samples (196) were analysed for the whole year, an increase of 40% from those analysed in 2014.

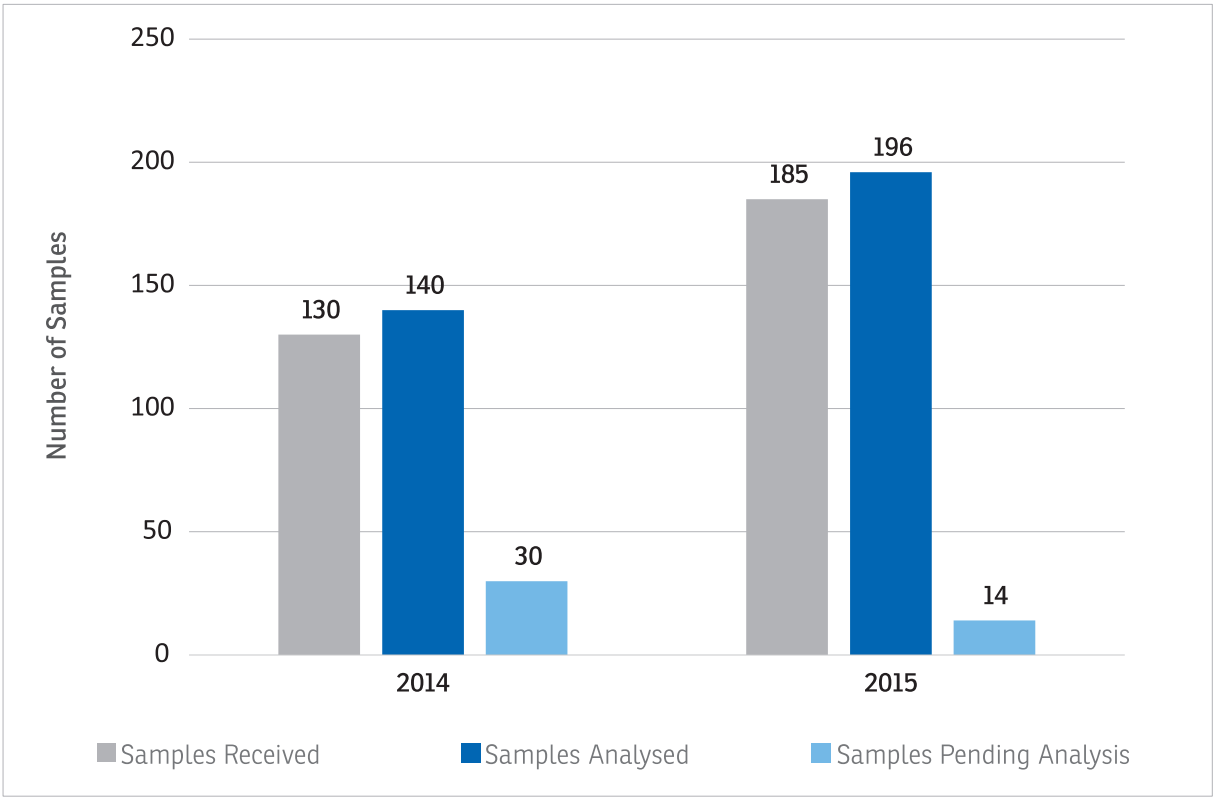


Figure 7: *Samples received for analysis in the Microbiology Laboratory*

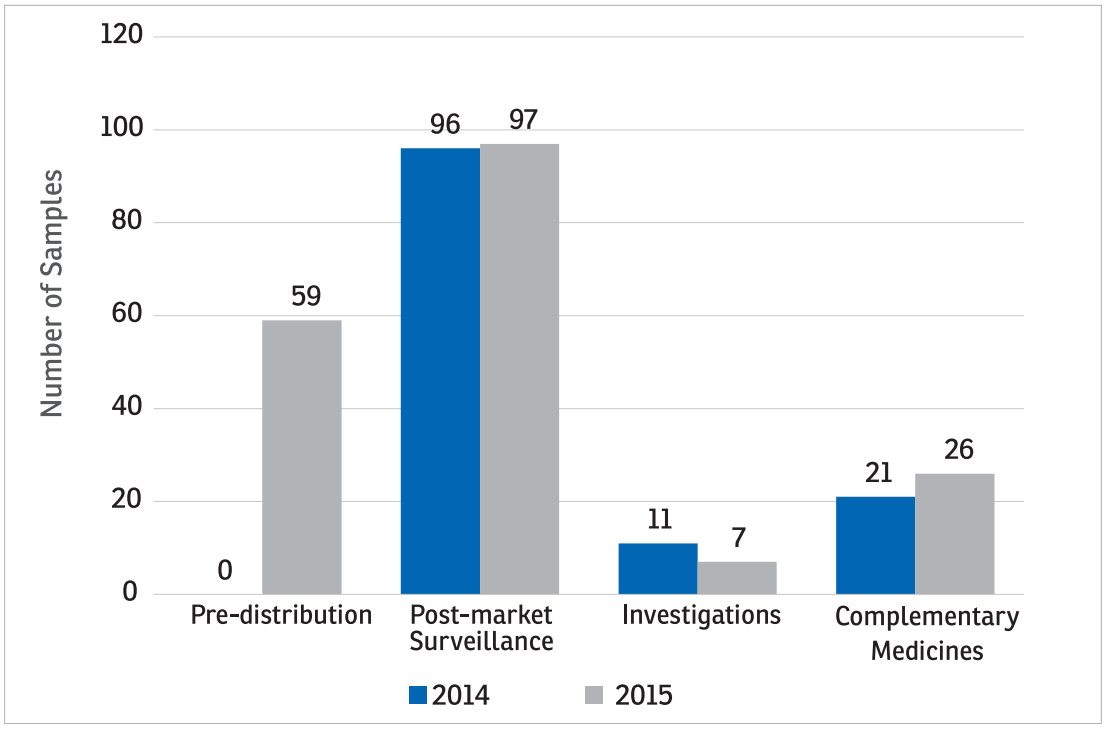


Figure 8: *Types of samples received for analysis in the Microbiology Laboratory*

Vaccine Lot Release

- Vaccines as biologicals require assessment per batch manufactured before approval for use. Hence every batch of vaccine imported has to be assessed for quality.
- The laboratory received and released fifty-five batches of vaccines for release, which was over two million doses of vaccine.
- 96 % of the batches received were from the MoHCC for the national immunisation programme and immunisation campaigns.

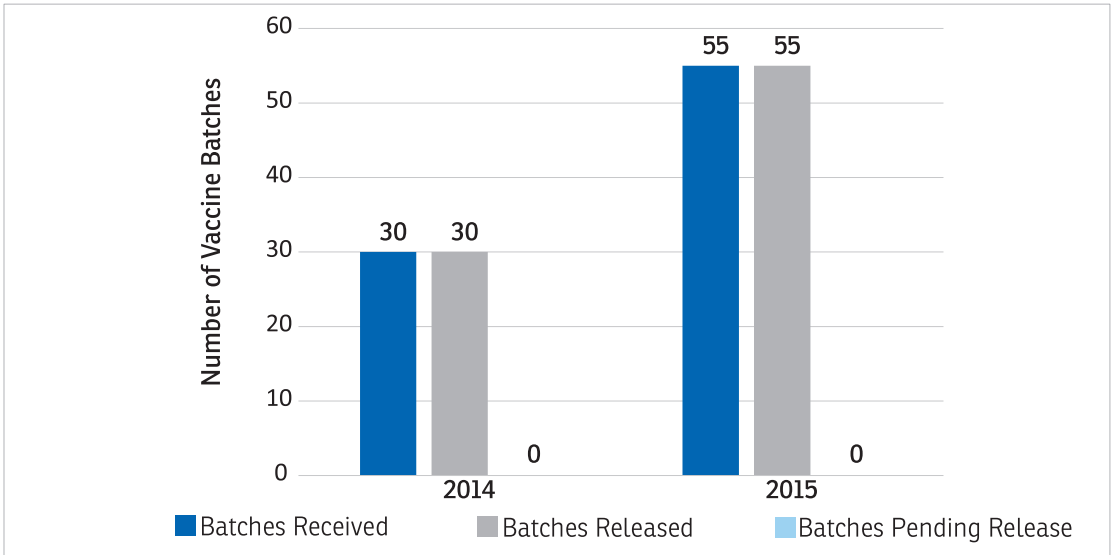


Figure 9: *Vaccine summary lot protocols received in the Microbiology Laboratory*

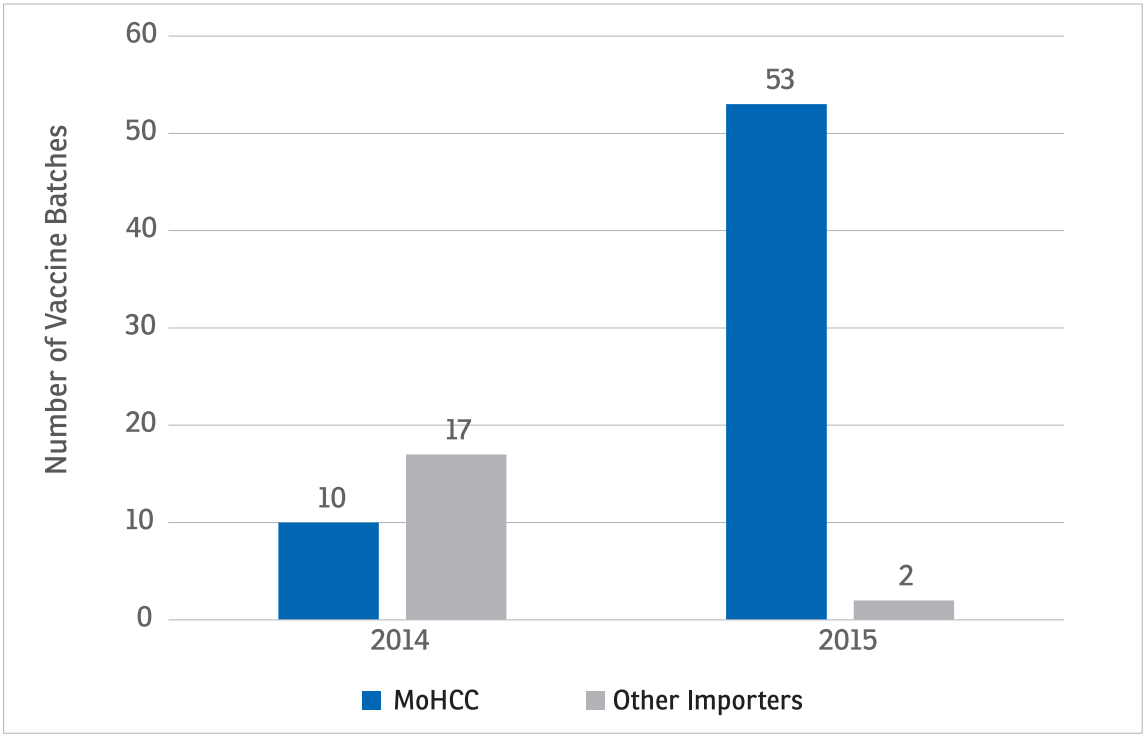


Figure 10: *Breakdown of Vaccine summary lot protocols received between MoHCC and other private importers*

Medical Devices Laboratory

The accredited Medical Devices laboratory examines gloves and condoms under the purview of the Medicines and Allied Substances Control Act [Cap 15:03]. The laboratory does conformity assessment of condoms and gloves as guided by the ISO requirements and MCAZ regulations. In addition the laboratory reviews applications for approval for use in Zimbabwe of condoms and gloves.

Condoms

Activities

- The laboratory received three-hundred and thirty (330) batches of condoms for testing in 2015, and managed to test three-hundred and twenty-six (326) batches. In 2014 the laboratory received three-hundred and thirty-six (336) batches of condoms for testing.

- The laboratory also received four batches of condoms for approval for use in Zimbabwe. All four were approved for use by the Registration Committee.
- The Minister of Health and Child Care, Dr. David Parirenyatwa commissioned the male condom testing equipment in the laboratory which was procured by the National Aids Council in 2014.

- The laboratory continued its participation in the annual proficiency testing schemes coordinated by Family Health International (FHI360), USA and Enersol of Australia.

- As part of the switch-over from the SANAS to the SADCAS, the laboratory hosted SADCAS auditors in August 2015 who audited the laboratory for compliance to ISO/IEC 17025. Accreditation was confirmed.

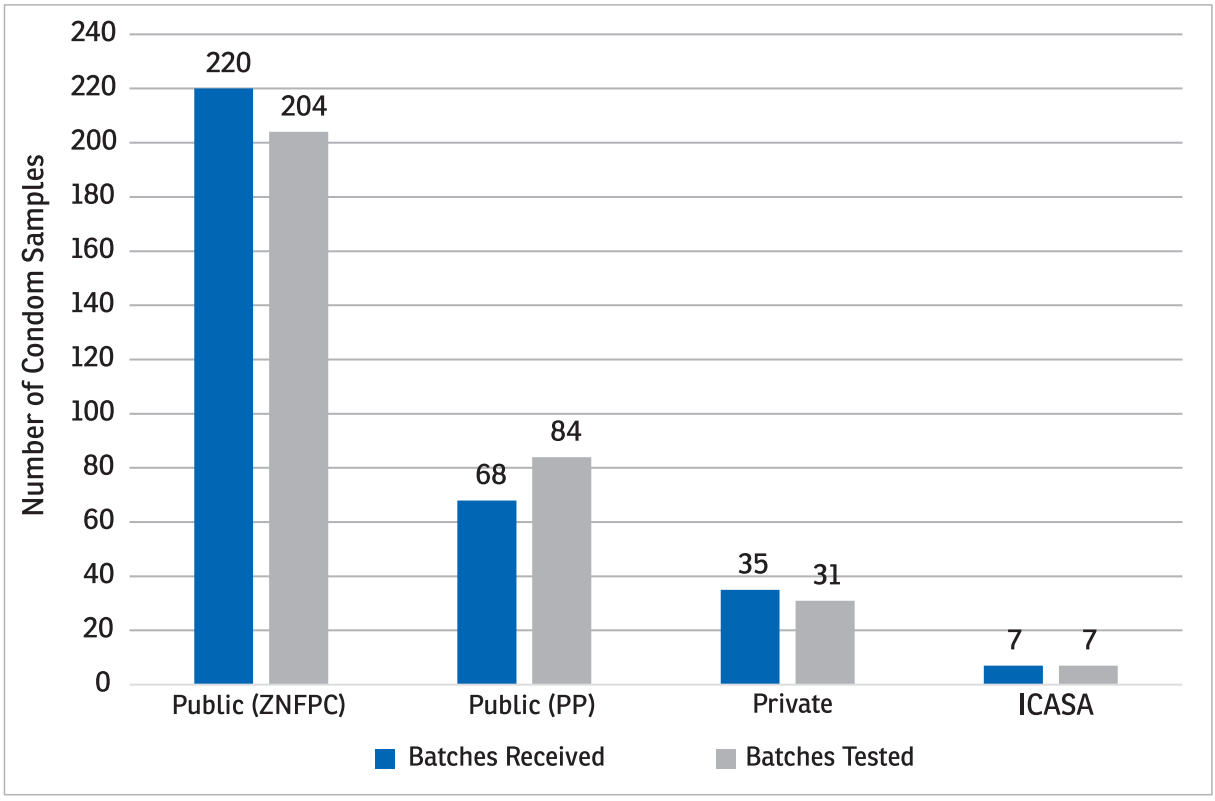


Figure 11: *Sources of condom batches received and tested in 2015*

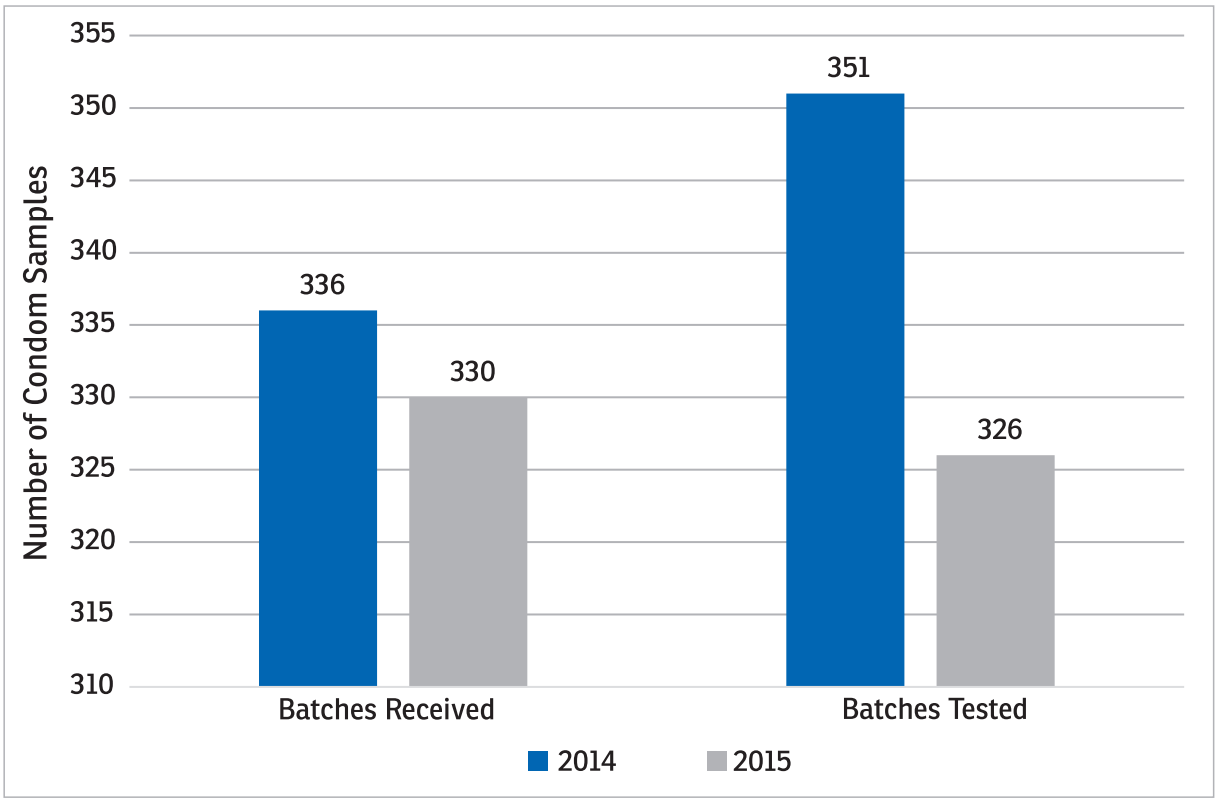


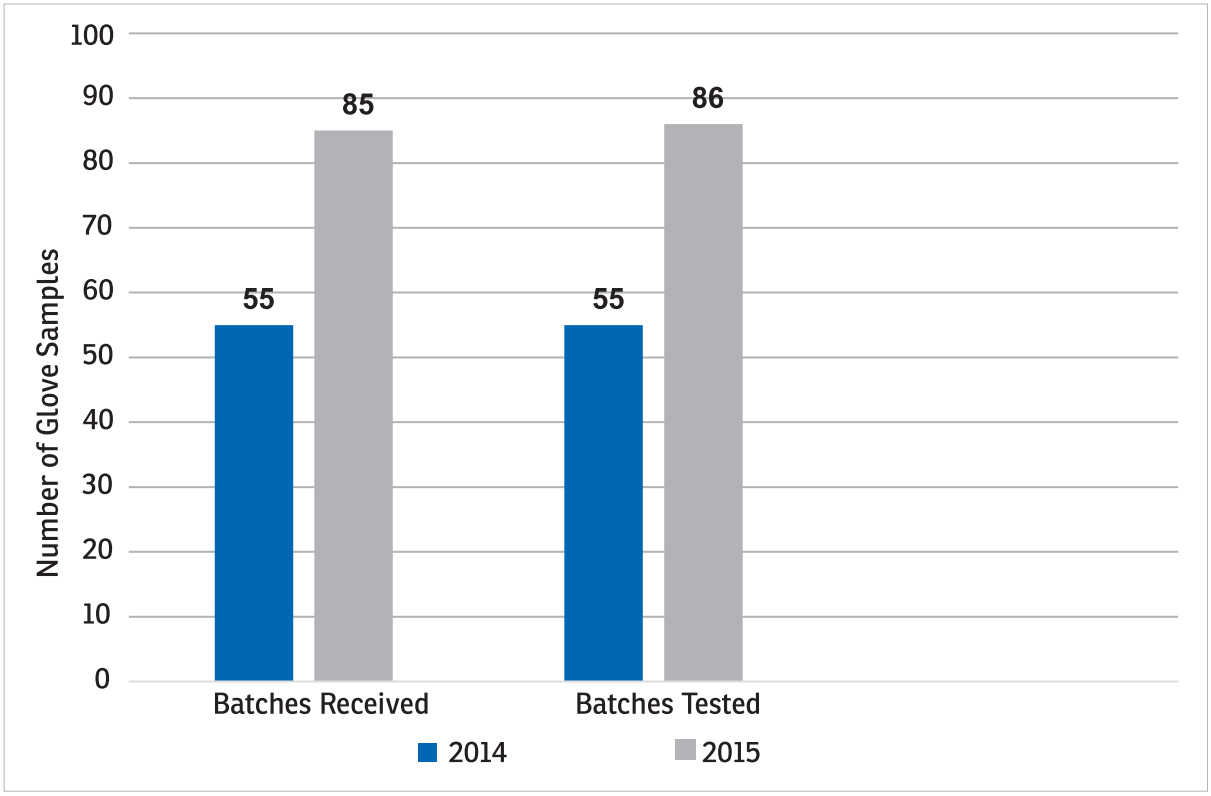
Figure 12: *Condom samples received for analysis in the Medical Devices Laboratory*

Gloves

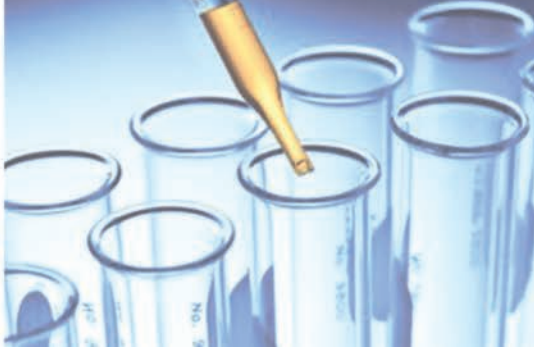
Activities.

- The laboratory received eighty-five batches of gloves for testing in 2015, and managed to test eighty-six batches, including one batch which was carried over from the previous year. Comparing the number of glove samples received for 2014 and 2015, there was an increase in the number received in 2015 than in 2014.

- Twelve batches were received for approval for use in Zimbabwe. Nine glove batches were approved by the Registration Committee, while three were not approved after failing conformity assessment tests.


100
90
80
70
60
50
40
30
20
10
0
Number of Glove Samples
55
85
55
86
Batches Received
Batches Tested
2014
2015





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