MCAZ Medicines Control Authority of Zimbabwe

ANNUAL REPORT

2017

Get in touch with us

Address: Medicines Control Authority of Zimbabwe
106 Baines Avenue
Harare
Zimbabwe

Tel: +263-242-736981/5; 708255; 792165

Mobile: +263 772 145191/2/3;

Fax: +263-242-736980;

Whatsapp: +263 772 256 303

E-mail: mcaz@mcaz.co.zw

Website: www.mcaz.co.zw

Facebook: @mcazofficial

Twitter: @mcazofficial

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Abbreviations

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

MMDU	Microbiology and Medical Devices Unit
MoHCC	Ministry of Health and Child Care
NEPAD	New Partnership for Africa's Development
NFM	New Funding Model
NMRAs	National Medicines Regulatory Authorities
NOMCoL	Network of Official Medicines Control Laboratories
OIE	Organisation Internationale de Epizooties
PFMA	Public Finance Management Act
PIM	Pharmacist Initiated Medicines
PMS	Post Market Surveillance
PP	Prescription Preparations
PQ	Prequalification Programme
PSI-Zim	Population Services International- Zimbabwe
PSZ	Pharmaceutical Society of Zimbabwe
PVCT	Pharmacovigilance and Clinical Trials
QMS	Quality Management System
RCORE	Regional Centre of Regulatory Excellence
SADC	Southern African Development Community
SADCAS	Southern Africa Development Community Accreditation Service
SANAS	South African National Accreditation System
SSFFC	Substandard/Spurious/Falsified/Falsely-labelled/Counterfeits
TB	Tuberculosis
tOPV	Trivalent Oral Polio Vaccine
TSR	Targeted Spontaneous Reports
UNDP	United Nations Development Programme
USP	United States Pharmacopeia
VAT	Value-Added Tax
ZEPI	Zimbabwe Expanded Programme on Immunization
ZIMRA	Zimbabwe Revenue Authority
ZNFPC	Zimbabwe National Family Planning Council
ZIMCODE	National Code on Corporate Governance for Zimbabwe
ZNFPC	Zimbabwe National Family Planning Council

CHAIRMAN'S STATEMENT

Mrs. Josephine Ncube
Chairperson, 2016 - 2017

I am pleased to provide a synopsis of the activities of the Authority (Board) and its Committees that enabled the Authority to deliver on its 2017 strategic objectives.

TWENTY-YEAR JOURNEY

The year 2017 marked the 20th anniversary as an autonomous regulatory body. The Authority commenced operations on 1st August 1997 as successor to the Drugs Control Council (DCC) and the Zimbabwe Regional Drug Control Laboratory. The commemorations allowed us to reflect on successes attained and the challenges that the Authority has overcome in the 20-year journey. The introspection helped the Authority plan for improvements as it strives to provide better and extended regulatory services within the limitations of our resources. Some of the milestones achieved were the award of ReCoRE status in 2014, retention of ISO 17025 accreditation throughout the five-year period, award of the WHO Prequalification for our laboratories in July 2014, continued participation in the NoMCOL /African Medicines Quality Forum (AMQF) throughout the five-year period.

CONSTITUTION OF THE BOARD

The Authority held a board induction workshop for new members who had been appointed to serve on the Board and Technical Committees. The induction ensured that the new members familiarize with the Authority's legal mandate, governance frameworks, and policies thus empowering them to effectively contribute. The end of 2017 marks the end of the three-year terms of office for the majority of our current Board members, giving rise to an opportunity for rejuvenation

BOARD MEETINGS

All the scheduled quarterly Authority Meetings were held during which the decisions of the various Committees were ratified. The Executive Committee, acting as the strategy committee, held scheduled meetings to monitor progress in implementation of the 2017 work plan and attainment of the set key milestones.

GOVERNANCE COMPLIANCE

The Authority discharged its functions within the framework of the national and institutional governance standards. The Authority grappled with the challenges of consolidating its final accounts for 2016 leading to delays and missed targets with respect to the finalisation of the audit report and publication of the annual report. I am pleased to note however that the final audit report was yet again not qualified.

SUSTAINABILITY

The Authority managed to fulfil its mandate and fund all its operations using revenue generated from operations without any subventions from the fiscus. In the fourth quarter of 2017, completion of a questionnaire for self-evaluation of state entities to enable government to rationalise parastatals and state entities indicated that the Authority was delivering on its mandate without being a burden on the fiscus. The continued support from development partners who support the parent Ministry's pharmaceutical supply programme and the Authority's Quality Assurance Program is appreciated. Through the Global Fund, the Authority managed to secure funding to renovate the microbiology laboratory as it strives to attain WHO Prequalification status and ISO 17025 accreditation. Support for quality assurance testing of medicines intended for the public sector has also been received through the Health Development Fund (HDF), managed by UNICEF.

REGIONAL HARMONISATION

The Medicines Control Authority of Zimbabwe was designated the host agency for the SADC Regional Harmonisation project by the Health Ministers from the region. This designation was an affirmation of the confidence the region has in the capabilities of the MCAZ to coordinate the planned regional activities. In the meantime the Authority continued to spearhead the SADC work-sharing initiative under the name Zazibona, which has seen several national medicines regulatory agencies within the regional economic group working together to reduce timelines to registration of medicines through a collective effort for the fourth year running. The initiative is now globally recognised and often quoted as a unique example of work-sharing and collaboration and efficient application of resources.

"The Authority managed to fulfil its mandate and fund all its operations using revenue generated from operations without any subventions from the fiscus."

COMPLEMENTARY MEDICINES REGULATION

Whilst the introduction of regulations on complementary medicines saw a number of applicants make the effort to submit product applications under the new regulations, it was the view of the Authority that full compliance was not achieved. All current and aspiring marketers of complementary medicines are continuously encouraged to submit applications for approval under the regulations.

ENFORCEMENT OF STATUTES

The Licensing and Advertising and Hearing Committees continued to hold meetings to deal with cases of poor supervision of premises, sale of unregistered and expired or illegal medicines, just to mention a few examples of cases. Depending on the severity of the offences, supervisors and directors of licensed premises were either sanctioned or, in extreme cases where the public was seriously endangered, supervisors and licence holders had their licences cancelled and directors disqualified from dealing in medicines for various periods.

I thank the Authority members, Committees, Management and Staff, our line Ministry, our external Auditors, our bankers, our legal advisors, technical cooperating and development partners, our suppliers and customers. Your support helps the Authority deliver on its mandate in spite of the sometimes-difficult operating environment.

J. C. NCUBE (MRS)

BOARD CHAIRMAN

DIRECTOR-GENERAL'S STATEMENT

Ms Gugu N. Mahlangu
Director General

It is my singular honour to present the MCAZ Annual Report for the year ended 31st December 2017, a year which marked the Authority's 20th Anniversary as an autonomous medicines regulatory body. I will highlight both the successes and challenges for 2017, the fourth year in a five-year (2014-2018) planning period.

SUSTAINABLE RESOURCE BASE

The 2017 revenue target of USD 4.1 million was attained. The Authority also managed to exceed its resource mobilisation target through provision of quality assurance and post marketing surveillance services to Ministry of Health and Child Care and technical and cooperating partners such as UNICEF and the Global Fund. The Authority witnessed an upsurge in operating costs in Q3 and Q4 of 2017 which undercut the savings that we strived to carry over to following year.

EFFECTIVE AUTOMATED SYSTEMS

The Authority successfully deployed the Employee Self Services (ESS) platform that allows our staff to access Human Resources services such as leave application, submission of overtime claim sheets, and accessing payslips online. The Authority also achieved 80% migration of the Zimbabwe Drug Information System (ZIMDIS) to the Structure Query Language (SQL) server. Through support from UNDP, development of an electronic Adverse Drug Reaction (eADR) reporting and electronic Clinical Trials (eCT) Registry system are currently underway. The main challenge included stagnation of Enterprise Resource Planning (ERP) programme due to poor local (in-country) support. Delays were also experienced in receipt of purchased ICT hardware and software due to price fluctuations in Q3 and Q4.

EFFECTIVE REGULATORY SYSTEMS

Processing timelines for issuing export permits were reduced from 5 to 2 days in a bid to support exports and foreign currency generation for local manufacturers. The Licensing and Enforcement Division retained a team of dedicated cGMP inspectors to reduce the lead time to inspection of local and external manufacturers. A dedicated team of Enforcement Officers to increase responsiveness and resolution of regulatory complaints was put in place. The Evaluations and Registration Division continued efforts to reduce the median timeline to registration from 18-20 months to 14 months. Variance in time to registration was mitigated by systematically closing a number of open applications accumulated over the years due to applicants' open-ended response time and lack of a reliable application tracking system.

A significant increase in applications for importation of unregistered medicines was also noted. This might signal foreign currency shortages leading to failure of importers of registered products accessing foreign currency and thus failing to supply registered products. A number of non-compliance of licensed persons and premises to adhere to Good Manufacturing Practices, Good Distribution Practices, Good Laboratory Practices, Good Dispensing Practices and Good Pharmacy Practices was also witnessed. Illegal sale of medicines by unlicensed persons in unlicensed premises such as street markets, persisted in spite of the public warnings to consumers and periodic blitz with law enforcement agents to confiscate medicines.

SKILLED AND COMPETENT PEOPLE

Overall staff retention remained unchanged at 95%. We utilised competency matrices to upgrade staff that had demonstrated consistently high performance. We also managed to refine the structures of the ICT Unit, the Chemistry Division and the Evaluations and Registration Division to increase efficiency in service delivery. Management and staff continued to receive invitations to attend WHO Expert Committees and technical working groups. This maintains the Authority's visibility at international fora where norms and standards for medicines regulation are discussed.

GOOD CORPORATE GOVERNANCE

The Authority received an unqualified audit report for 2016. The Authority was recognised for its speedy responsiveness in implementing Rapid Results Initiatives (RRI) by lowering the processing fee issuance of medicines export permit. The Authority successfully retained its ISO 17025 accreditation for the Chemistry and Medical Devices Laboratories.

VALUE FOR MONEY SERVICES

The Authority established a vibrant Public Relations team which increased its visibility to local stakeholders on various platforms including traditional and digital platforms. Staff in the Pharmacovigilance and Clinical Trials Division (PVCT) published an article 'A comparison of Adverse Drug Reactions profiles for patients on antiretroviral and anti-tubercular treatment in Zimbabwe' in a peer reviewed journal, Clinical Drug Investigation. An analyst in the Chemistry Division published an article, 'A quality control study of ibuprofen tablets available in the formal and informal market in Harare, Zimbabwe' in the African Journal of Pharmacy and Pharmacology. This is in line with the Authority's staff development strategy which urges staff to be reflective practitioners that generate and share new knowledge gained as they solve public health problems.

The Authority also conducted the second independent external customer satisfaction survey and the results highlighted that there was room for improvement in terms of customer service delivery in the various Divisions and Units of the Authority. Some of the findings corroborated the findings of the Good Governance of Medicine Survey commissioned by the Ministry of Health and Child Care. The Authority started addressing the expressed needs of its valued stakeholders and it is envisaged that automation of key processes will solve most of the perceived weaknesses. By harnessing ICT and e-governance tools it is hoped that the Authority will be able to develop a more user-friendly website, increase public awareness on dangers of street vending of medicines and improve customer service delivery.

I want to thank the Authority members, the Management Team, all staff members and stakeholders for making 2017 yet another success.

G. N. MAHLANGU (MS)

MCAZ DIRECTOR-GENERAL

GOVERNANCE AND RISK REPORT

The Board recognizes that in order to effectively bring value to the Authority' strategy and business, it must observe good corporate governance, effective risk management systems and a sound control framework. The limited resources at the Authority's disposal calls upon the Authority to put in place responsive governance systems for it to fulfill its national mandate. The Authority within the framework of accountability aims to achieve its strategic objectives with the maximum level of effectiveness and efficiency to attain, among other things:

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

The Authority is also cognizant that for this framework to achieve its purpose, continuous monitoring, and mechanisms to identify any risks (upside and downside) are imperative. Appropriate responses are formulated for risks (downside) that can hamper the achievement of the strategic objectives. Any upside risks identified are exploited and built into the strategies of the Authority for the benefits of the Authority. The Board as part of its mandate continues to give importance to the principles of transparency, integrity, and accountability in accordance with the requirements set out by the Medicines and Allied Substance Control Act (MASCA) Chapter (15.03) and other laws, regulations, standards and best practices among others:

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

This enables the Authority's stakeholders to derive the assurance that in executing its mandate the Authority is being governed 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 Board is committed to ensuring that the 30 June deadline to produce the financial statements is met in future years.

THE BOARD OF DIRECTORS

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

The Board is ultimately responsible for the strategic direction of the Authority and is accountable to the Minister of Health and Child Care and is responsible for formulation of the Authority's strategic plans. Its role is to foster effective decision making processes and policies within the Authority. The Board is thus proactive and effective in the policy making process. Board meeting procedures are not only focused on reviewing past performance but also on debating new decisions, strategies and policies and ensuring that set targets and goals are realized.

Board is characterised by:

Expertise

- sufficient to allow the Board to add value to policy direction, effective oversight on the Authority's performance and the decision-making process

Procedures

- that foster open debate and keep Board Members informed and attuned to the Authority's operations and stakeholders' concerns.

The Board works collaboratively with the Management team through harnessing its collective intellectual power in dealing with complex matters. The Board and the Management team steer themselves toward farsighted strategic goals. They thus exercise their broad knowledge and accumulated wisdom on a wide range of domains; strategy, regulatory, legal, finance, human resources, technology and the like.

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.

How often does the board meet?
At least quarterly to evaluate performance, assess risks and hold additional meetings where necessary to shape the strategic direction of the Authority and its

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.
The current composition of the Board is as follows;

Table 1: MCAZ Board members 2017

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
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 and Child Care)	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
Dr.C.S. Mutisi	Section 4(1) (Any other)	01/03/2017
Ms.J. Chidora	Section 4(1) (Any other)	01/03/2017
Mr.D. Mandishona	Section 4(1) (Any other)	02/02/2015 (Resigned Jan 2017)
Mrs. D. Mandaza	Legal Adviser	

BOARD COMMITTEES

The Board, in line with good Corporate Governance has established and delegated certain responsibilities and functions to sub-committees with specific composition and reporting requirements. However, it 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 these committees to provide diversity and add depth to the quality of committee debates. The Board Committees are chaired by a member of the Board and members of the Management Team attend meetings as appropriate.

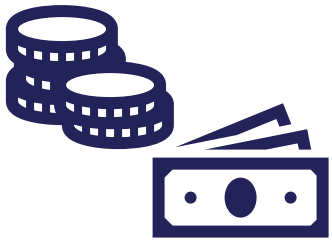
AUDIT COMMITTEE

The Audit Committee has an objective, independent role in keeping with its terms of reference. In accordance with these terms of reference, the committee assists the Board in fulfilling its oversight responsibilities for financial reporting, the governance, risk management and control (GRC) processes, the audit process and, as appropriate, the Authority's compliance with laws and regulations. It is chaired by an independent non-executive director. The external and internal auditors meet regularly with and have unrestricted access to the audit committee.

HUMAN RESOURCES COMMITTEE

The Committee ensures the establishment, through recommendations to the Board, of a formal and transparent procedure for developing a policy on recruitment, remuneration, performance evaluation, staff welfare, health and safety and any other human resources issues for the Authority. The Committee also ensures that the appropriate organisational structure is in place to achieve the Authority's goals.

FINANCE COMMITTEE



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

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.

Table 2: Board and Committee Attendance (From 1st January, 2017 to 31st December, 2017)

NAME OF MEMBER	BOARD		AUDIT		HUMAN RESOURCES		FINANCE	
	Attended	Possible	Attended	Possible	Attended	Possible	Attended	Possible
Mrs. J. Ncube	3	4			4	5		
Dr. A. F. Zinanga	4	4					5	6
Dr. P Muvavarirwa	3	4			4	5	6	6
Mrs J. Chaibva	3	4	2	5				
Dr. P. Chonzi	2	4	4	5				
Dr. R. Gwisai	4	4			5	5		
Dr. C Pasi	3	4						
Mrs. R. Hove	2	4						
Dr. C.C. Maponga	2	4						
Mr. J Kunonga	4	4	6	6	4	4		
Dr.C.S.Mutisi	2	3					5	6
Ms.J.Chidora	2	3						
*Mrs. D. Mandaza**	4	4						
Mr. F. Gwiza			5	5				
Mr. C. D Mahofa			5	5				
Mr. E. Jinda					4	5		
Mrs. F.Chinogurei					3	3		
Mr. I Ruzengwe							5	6
Mr. C Shoniwa							5	6

**Legal adviser to the Board*

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;

Table 3: MCAZ Management Team

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	Head - Human Resources Division
Ms. C. Mugwira	Legal Manager **(Resigned 30th June, 2017)**
Mr H. Ngwarai	Head - Internal Audit Unit
Mr T. Nyovhi	ICT Manager
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.

Subscription to Deloitte TIP Offs Anonymous

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

Internal Audit

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

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

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

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

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 Financial Statements Of The Medicines Control Authority Of Zimbabwe For The Year Ended December 31st, 2017, can be found in Annexure 1 of this report.

HUMAN CAPITAL

HUMAN RESOURCES COMMITTEE

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

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

- Remuneration
- Long Service Award
- Allowances
- Leave of Absence
- Vehicle and Fleet Management

The total staff establishment during the reporting period was 120 and as of 31st December, 2017, there were three vacant positions.

Table 3: The Authority's staff establishment as of 31st December 2017

Division/ Unit	*Gender*		*Approved Number of Posts*
	M	*F*	
Director-General's Office	0	2	3
Projects and Public Relations	1	0	1
Human Resources	1	1	2
Quality Systems	0	3	3
Internal Audit	1	0	1
Microbiology & Medical Devices	5	5	12
Evaluations& Registration	10	11	21
Licensing& Enforcement	10	8	18
Pharmacovigilance & Clinical Trials	6	5	11
Chemistry Lab	7	8	15
Finance	4	3	7
Administration	14	5	19
Information, Communication & Technology	3	1	4
Legal & Corporate Affairs	0	3	4
TOTAL	62	55	120

In addition to the approved positions, the Authority had three (3) project funded positions two (2) in Pharmacovigilance and Clinical Trials (PVCT Division) and one (1) in Projects and Public Relations as well as five (5) Graduate Interns and six (6) pre-registration pharmacists respectively.

DIVISIONAL REPORTS

Evaluation & Registration

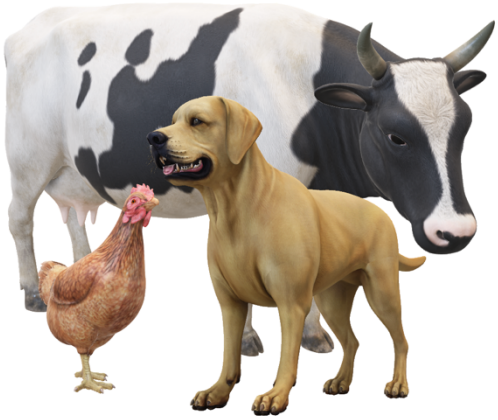

Human Allopathic Medicines

The Human Allopathic Medicines Unit of the Evaluation and Registration Division ensures that human allopathic 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 incorporate principles from the SADC Harmonisation Registration Guidelines and the WHO Prequalification Guidelines. For novel products whose safety, quality and efficacy may not be well addressed by the above guidelines, MCAZ selectively applies relevant requirements expounded in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines.

Human Medicines Registration Summary from 2017

- 292 Number of new applications for registration of Human Medicines
- 204 Number of products registered (including prior years)
- 113 Number of products refused registration (including prior years)
- 68 Number of products withdrawn

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



Veterinary Products

The veterinary unit is a sub-function of the Evaluation and Registration Division. It is responsible for assessing the safety, efficacy and quality of veterinary medicines and issuing marketing authorisation for veterinary medicinal product. In 2017, the unit received a significant drop in applications for registration of veterinary medicinal products in comparison to the previous years. Despite this decrease, the unit participated in numerous regional and international seminars on harmonisation of veterinary medicinal products which provided opportunities for Zimbabwe and other Southern African Development (SADC) Community states to harmonise registration of veterinary medicinal products. In addition, MCAZ joined the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Outreach Forum in April 2017. The veterinary unit plans to use its presence at the VICH Outreach Forum to advocate for the development of international standards for registration of acaricides, medicated premixes and feeds. The Unit submitted annual statistics to the OIE Global Database on types and consumption patterns of veterinary antimicrobials used in Zimbabwe. The Unit also published the veterinary medicinal products register on the MCAZ website for the benefit of applicants and wholesalers.

Veterinary Medicines Registration Summary from 2017

- 11 Number of new applications for registration of Veterinary Medicines
- 15 Number of products registered (including prior years)
- 15 Number of products refused registration (including prior years)
- 2 Number of products withdrawn

Complementary Medicines include herbal, nutraceutical, homeopathic and anthroposophic medicinal products used as adjunct to treatment with allopathic medicines. They are approved under the Complementary Medicine Regulations, SI 97 of 2015. The provisions in the SI allowed products which were already on the market before gazetting of the SI on 15 September 2015 to stay on the market, provided complete new application, in accordance with new regulations, were submitted to the Authority within a stipulated timeline. The products were thus temporarily listed and allowed stay on the market pending the final outcome of evaluation of full dossiers. The final outcome will be either issuance of an approval certificate or refusal to issue an approval certificate and revocation of the right to access the market. Enforcement activities ensued to remove products that had no provisional or substantive legal authority to access the market.

Complementary Medicines Registration Summary from 2017

- 45 Number of new applications for registration of Complementary Medicines
- 54 Number of products approved (including prior years)
- 21 Number of listed products
- 0 Number of products withdrawn

Other key highlights

- The Division created a specialised team of biotherapeutic product assessors in response to the growing numbers and complexity of assessment of biotherapeutic products
- MCAZ assessors continue to received exposure to WHO Prequalification training and active participation in dossier review
- As a Centre of Regulatory Excellence designated by the African Medicines Regulatory Harmonisation (AMRH) of NEPAD Agency of the AU, the Evaluations Divisions provides hands-on training on Quality and Bioequivalence dossier evaluation in October every year
- The Division continued to actively participate in the One Health Antimicrobial Resistance (AMR) Core Group and Technical Working Groups.

Zazibona Collaborative Registration Process

Participated in the 4 annual sessions

44 new product request for channelling through ZAZIBONA

MCAZ was lead assessor for **10** products

22 approvals, **3** rejections and **3** withdrawals

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 reviews the outcome of the meetings and any lessons learnt are applied to enhance continuous improvement and customer focus.

Registration Timeline

*This is inclusive of the manufacturers' time to respond to queries.

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.

1,240
licenses and permits issued in 2017

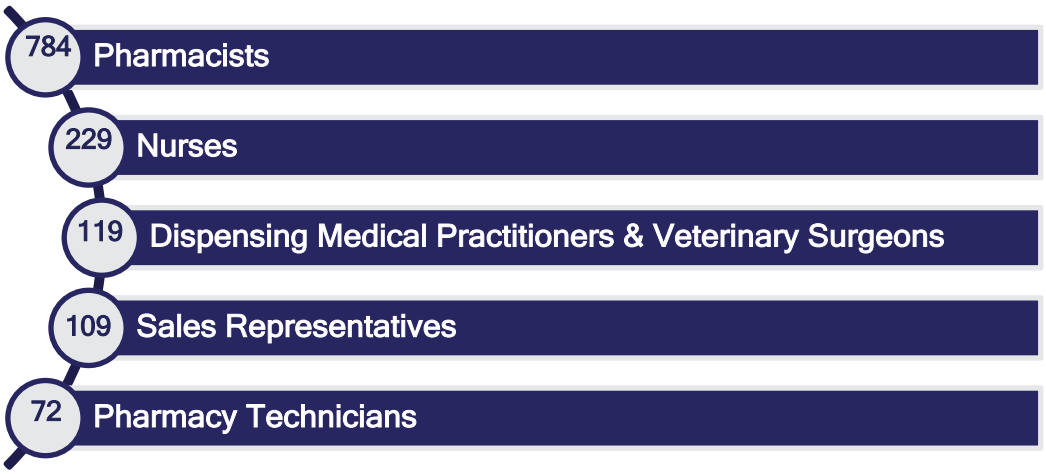
↓ by 2.5%

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.

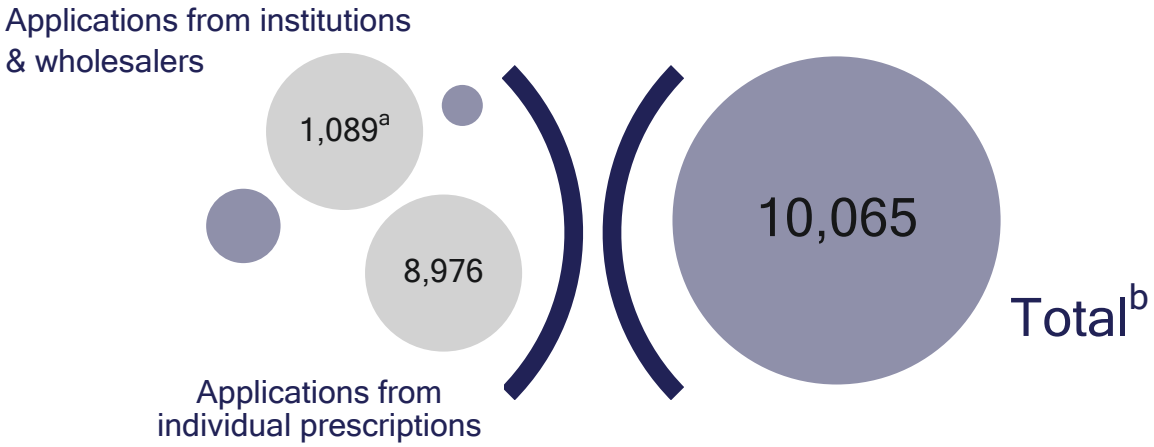
1,310
licenses and permits issued in 2017

↑ by 34%



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.



[a] *Some of these were for registered products with non-complaint labelling on importation.*

[b] *Increase of 33.9% from those processed in 2016, which is attributed to the economic hardships with most wholesalers unable to import registered medicines and individuals resorting to unregistered alternatives.*

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.

***142** Approved donations for entry into Zimbabwe*

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.

101 Number of licences to import narcotics and psychotropic substances

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

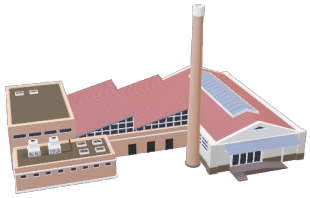
257 Number of permits for the importation of precursor substances were issued.

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.

960 • Inspections of licensed premises

960 in 2017 vs 866 in 2016



237 • Inspections of public health institutions

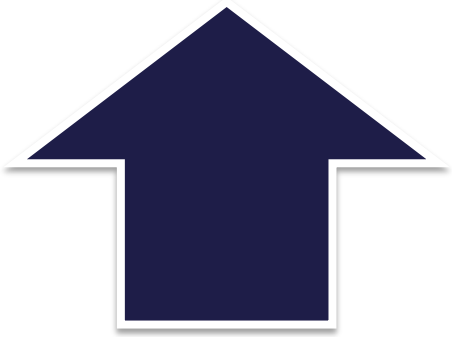
237 in 2017 vs 165 in 2016

140 • Special investigational inspections

140 in 2017 vs 136 in 2016

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.



91 export permits

1182 import permits

- 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 medicinal consignments at the ports of entry.

Pharmacovigilance and Clinical Trials

The MCAZ has a mandate to monitor the quality, safety and efficacy of medicinal products and medical devices after they have been registered and launched onto the market. This is achieved through the Pharmacovigilance and Clinical Trials Division (PVCT). The PVCT Division is responsible for pharmacovigilance, post marketing surveillance, regulation of clinical trials of medicines and medical devices, processing applications for variations of registered medicines and re-instatements of cancelled products. The division also ensures communication of changes in risk/benefit balance to stakeholders with a view of promoting patient safety including rational and safe use of medicines, vaccines and complementary medicines.

Pharmacovigilance

Zimbabwe, through MCAZ, became a participating country to the World Health Organisation (WHO) International Drug Monitoring programme in 1998. The MCAZ serves as the national pharmacovigilance centre. The operations of the centre are based on the WHO guidelines for setting up and running a national pharmacovigilance centre.

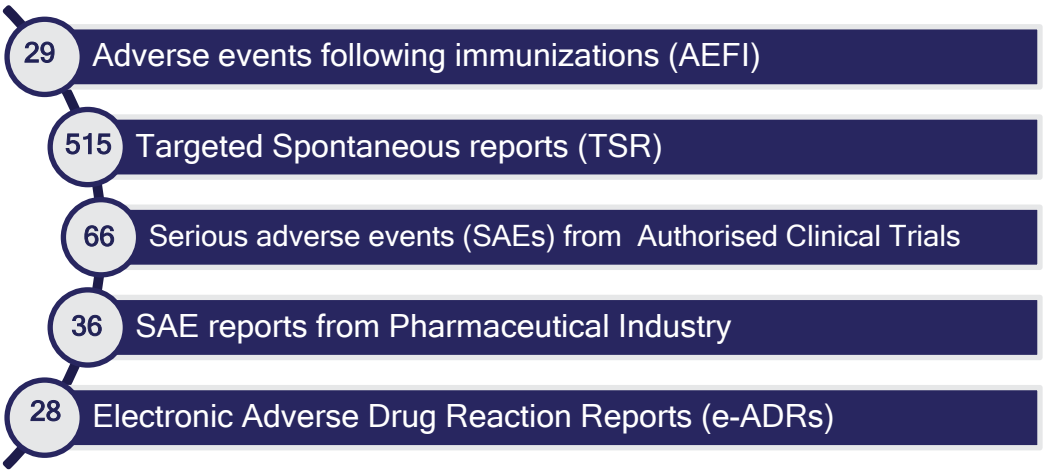
Reports on adverse drug reactions received from healthcare professionals and patients are evaluated and entered in the WHO Uppsala Monitoring Centre database called Vigibase. The PVCT division ensures that the reporters receive appropriate feedback.

We wish to acknowledge all stakeholders in pharmacovigilance, especially the Ministry of Health and Child Care and all inter-governmental agencies such as the WHO and Global Fund (GF) in supporting pharmacovigilance activities in Zimbabwe. Of note is the Targeted Spontaneous Reporting (TSR) programme under Global Fund. The success of the pilot phase from October 2012 to September 2013 resulted in the need to expand the programme beyond ARVs and anti-TB medications. The program now enables reporting of adverse drug reactions of essential medicines in the Essential Drugs List in Zimbabwe (EDLIZ). Through the programme and trainings conducted we have managed to sensitize healthcare practitioners in pharmacovigilance.

The WHO Programme for International Drug Monitoring consists of more than 150 countries that collaborate internationally to monitor and identify the harm caused by medicines, to reduce the risks to patients and to establish worldwide pharmacovigilance standards and systems. Zimbabwe became a participating country to the programme in 1998

Source: Uppsala Monitoring Centre.
https://www.who-umc.org/

674
Individual Case Safety Reports (ICSR) received in 2017



Targeted Spontaneous Reporting (TSR) program

The Targeted Spontaneous Reporting (TSR) Program for ARVs, anti-TB and other Essential Medicines has been running successfully and has seen an increase in the number and quality of Adverse Drug Reports (ADR) that have been received by the Pharmacovigilance team.
A total of 194 health facilities and 920 health care professionals were trained from 2012 to 2017 in all provinces.

Eight TSR trainings of health care professionals were conducted in 2017. The aim of the trainings were to educate, encourage and remind all health care professionals to continuously participate effectively in the reporting of Adverse Drug Reactions (ADRs), and preparation of setting up regional sentinel sites.

The figure below indicates the total number of TSR reports received by the MCAZ and the reporting professionals:

← 16

← 7

← 3

Of the 543 reports received in 2017, 80% were reported by nurses. All the reports were evaluated for causality assessment by the PVCT Committee. Reporters were sent feedback on the assessments. In the 2017 bulletin three articles were included on the information gathered from these reports to as a way of disseminating information obtained from the reports.

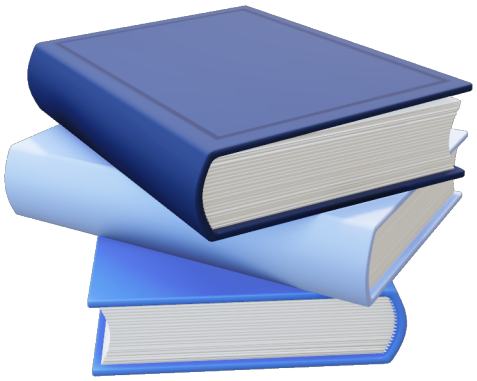
Adverse Events Following Immunisation (AEFI) Surveillance

Vaccine pharmacovigilance is a critical aspect in public health and a key indicator for pharmacovigilance systems. The MCAZ in collaboration with the Expanded Programme on Immunization- Ministry of Health and Child Care (EPI-MoHCC), have continuously worked to develop vaccine pharmacovigilance in Zimbabwe through participation in World Health Organisation (WHO) projects, development and implementation of the Adverse Events Following Immunisation (AEFI) surveillance guidelines and conducting trainings for health care professionals on AEFI reporting and case investigations.

In 2012, WHO developed a revised methodology for causality assessment of AEFI. The new method proposed by WHO uses a four-step process and allows the National Committees to review AEFI cases and guide the assessors on their causality. An electronic AEFI causality assessment software based on WHO methodology was developed by WHO to assist the assessors in their evaluation of individual cases of AEFI. In 2016 MCAZ adopted this new causality assessment system. Also following recommendations from the November 2015 WHO training on the new AEFI causality assessment method the AEFI surveillance guidelines were revised to provide guidance to all health workers on the management of AEFI, and submission of complete AEFI forms and case investigation forms and to enable causality assessment of the AEFI and risk-benefit assessment. In 2017 the Adverse Events Following Immunization Surveillance Guidelines were published. Trainings on AEFI case investigation and surveillance were conducted by MCAZ and EPI in Mashonaland west, Masvingo, Midlands and Manicaland. There was a decrease in the number of AEFI reports received by MCAZ from 138 in 2016 to 29 in 2017. This could be attributed to the fact that there were no vaccine campaigns in 2017.

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

An inter-country study to assess the inter-ratter reliability of the WHO AEFI causality assessment methodology and the utility of the new WHO AEFI causality assessment software was done. The Broad objective was to determine the reliability of the Adverse Events Following Immunization (AEFI) WHO causality assessment tool 2013 algorithm. The results were presented and adopted at the WHO – Global Advisory Committee for Vaccine Safety (GACVS) meeting on 6th December by Dr N.K Arora (India) and Priscilla Nyambayo (Zimbabwe). The findings were used to revise the WHO - AEFI manual and e-causality assessment worksheets.



Guidelines and Publications

The MCAZ published the first edition of the Good Clinical Practice (GCP) Guidelines to be used in clinical research in Zimbabwe in 2012. Since then the research area has rapidly evolved with a large number of clinical trials being conducted in Zimbabwe. In 2017 the PVCT division revised the guidelines in line with current local and international standards. The draft guidelines are expected to be finalized in 2018. The guidelines for application for variations to registered medicines were also revised to cater for the current requirements.

Automation of Systems

In 2017 MCAZ through support from the Global Fund, kick started the development of an electronic ADR reporting and electronic Clinical Trial Application registry platform. The aim was to increase the ease of doing business and to come up with user friendly e-ADR data management systems and Clinical Trial Applications system. The implementation partners for these systems are IntelliSOFT Consulting Group based in Kenya. The electronic ADR reporting allows online and offline reporting and was expected to be launched in 2018.

Post-Registration Variations and Applications for Re-Instatements

Applications for variations are evaluated by PVCT and tabled for approval by the Registration Committee. The current average processing timeline are three months from the date of receipt for local manufacturers, minor and administrative variations and safety updates, and twelve months for major variations.

- In 2017, 444 applications for approval of variations to registered medicines were submitted. There was a decrease in the number of applications received for variations to registered medicines from 657 in 2016 to 444 in 2017.

- 669 variations were processed and this include the backlog from 2014. This was a major improvement as compared to 2016 when 346 amendments were processed.

- 261 variations including some from the 486 which were brought forward from 2016 were still under review owing to the submission of inadequate information by applicants and also due to non- payment of variation fees. A total of three applications for re-instatement of registration of cancelled products were received and all were processed.

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.

Notification in writing is required if a medicinal product is no longer to be distributed and the registration of the product is to be cancelled.

Foreign Products 91% in 2017 VS. 94% in 2016	Payment of Retention Fees	Foreign Products 91% in 2017 VS. 84% in 2016
Local Products 99% in 2017 VS. 85% in 2016		Local Products 98% in 2017 VS. 96% in 2016
HUMAN MEDICINES		VETERINARY MEDICINES
43 in 2016 VS. 103 in 2017	Cancelled Products	26 in 2016 VS. 21 in 2017

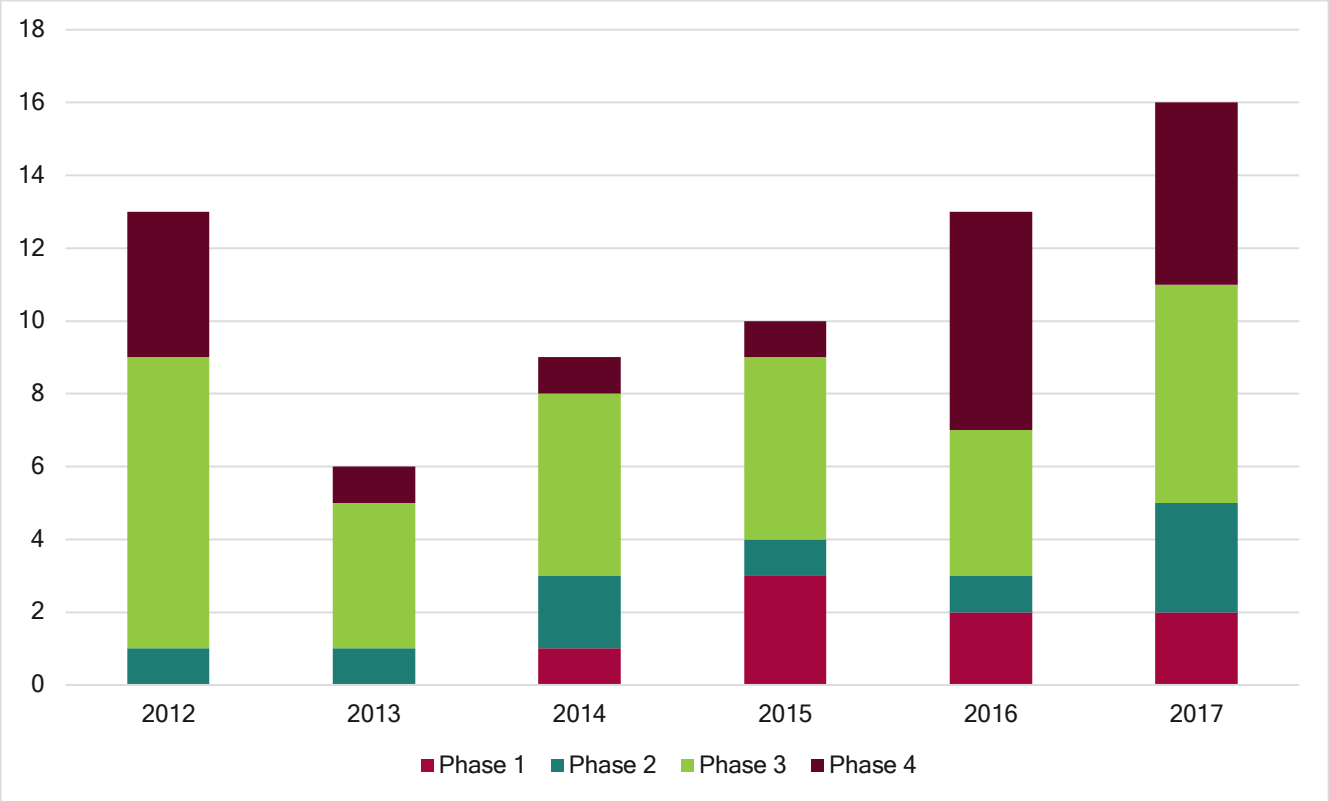
As highlighted above there was a considerable increase in collection of retention fees in 2017 as compared to the year 2016.

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. CT timelines were improved, average processing time for authorization of a study in 2017 was 78 days and the target was 90 days. 6 officers were trained by EMA on Online EU GCP Inspectors' Basic Training Course and 6 subsequent GCP inspections were conducted.

Sixteen clinical trial applications were received and authorised. Two were Phase 1 studies, three were Phase 2 studies, six were of Phase 3 studies and five were Phase 4 studies.

Distribution of phases for applications from 2012 to 2017



	2012	2013	2014	2015	2016	2017
Phase 1			1	3	2	2
Phase 2	1	1	2	1	1	3
Phase 3	8	4	5	5	4	6
Phase 4	4	1	1	1	6	5

Compliance with GCP is being monitored through processing of SAEs, amendments to clinical trial protocols, clarification memos, protocol deviation reports, progress reports and review of data safety monitoring board reports.

Laboratory

Chemistry Laboratory

The Medicines Control Authority of Zimbabwe owns a Chemistry Laboratory that participates in the strengthening of medicines regulation in Zimbabwe in collaboration with various stakeholders to improve on the availability of safe, effective and quality-assured products. The main objective being to participate in strengthening local capacity by carrying out key quality assurance functions and activities mainly in the registration, inspections of manufacturers of medicines and their distributors and post market surveillance.

The outcome in this collaboration is an improved Public Health sector:

i) Supply of safe, effective and good quality medicines
ii) Patients are protected from substandard and falsified medicines
iii) Evidence- based regulatory decisions are increased and made.
iv) Sustainable risk- based post marketing surveillance programs

Poor quality medicines for diseases like malaria, tuberculosis can lead to treatment failure and drug resistance. Hence laboratory competence is therefore essential to ensure laboratory results are accurate and acceptable. MCAZ laboratory has thus acquired the necessary ISO17025 accreditation and WHO prequalification quality standards to eliminate incidences of false results and also provide Public confidence in the regulator and increase of supply security.

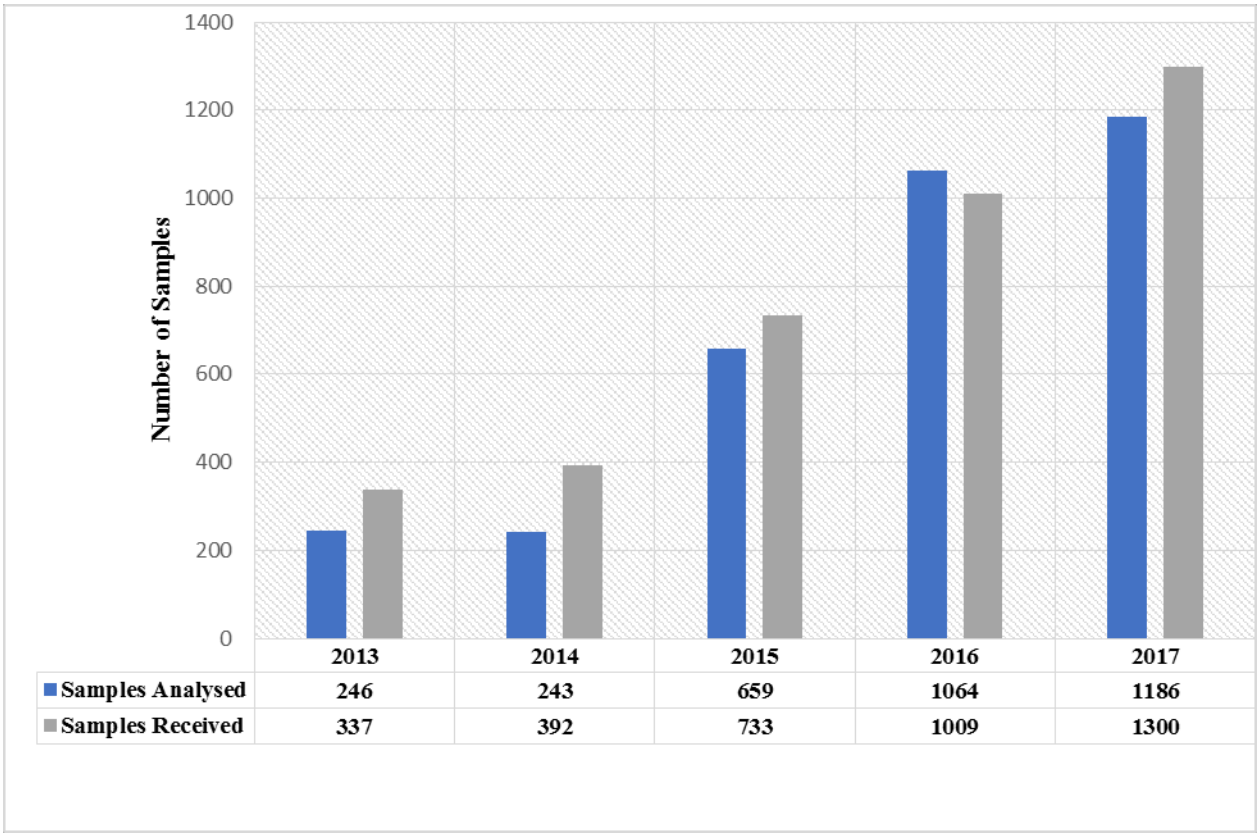
Medicines collected across all provinces were tested as a way of monitoring quality, safety and efficacy and manufacturers whose products were substandard were identified and GMP followed.

Inter-Laboratory Proficiency Testing

In the year 2017 the Chemistry Laboratory participated in twos inter -laboratory proficiency testing schemes conducted by NOMCoL Africa and KNMP and the outcome was satisfactory.

Laboratory Statistics

Figure 1.1: Graphical Presentations of Samples Analysed and Received (2013-2017)



	2013	2014	2015	2016	2017
Samples Analysed	246	243	659	1064	1186
Samples Received	337	392	733	1009	1300

Comment:

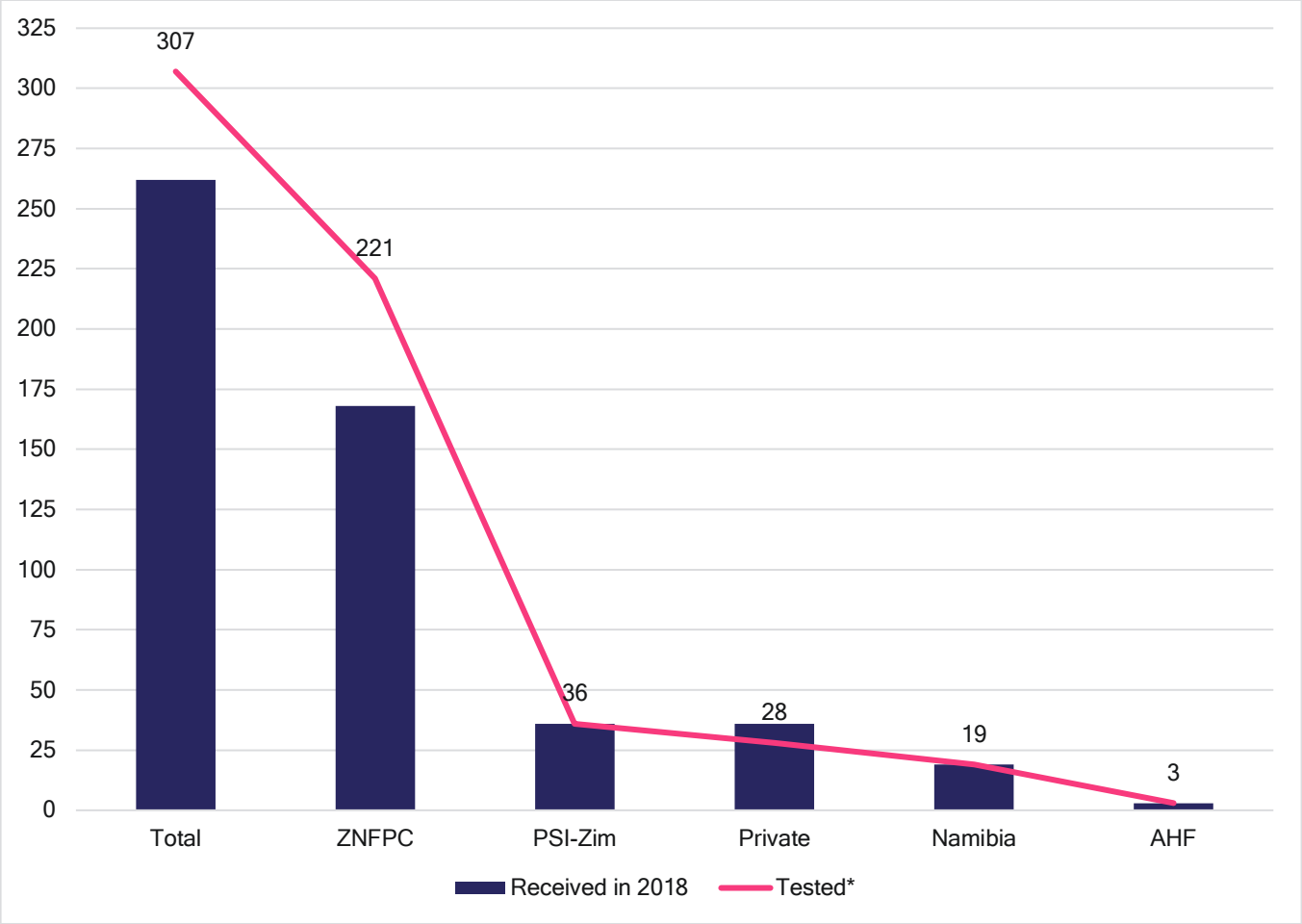
The 2017 productivity of the laboratory was slightly above that for 2016.

Microbiology and Medical Devices Unit

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

Highlights

Condoms received and tested

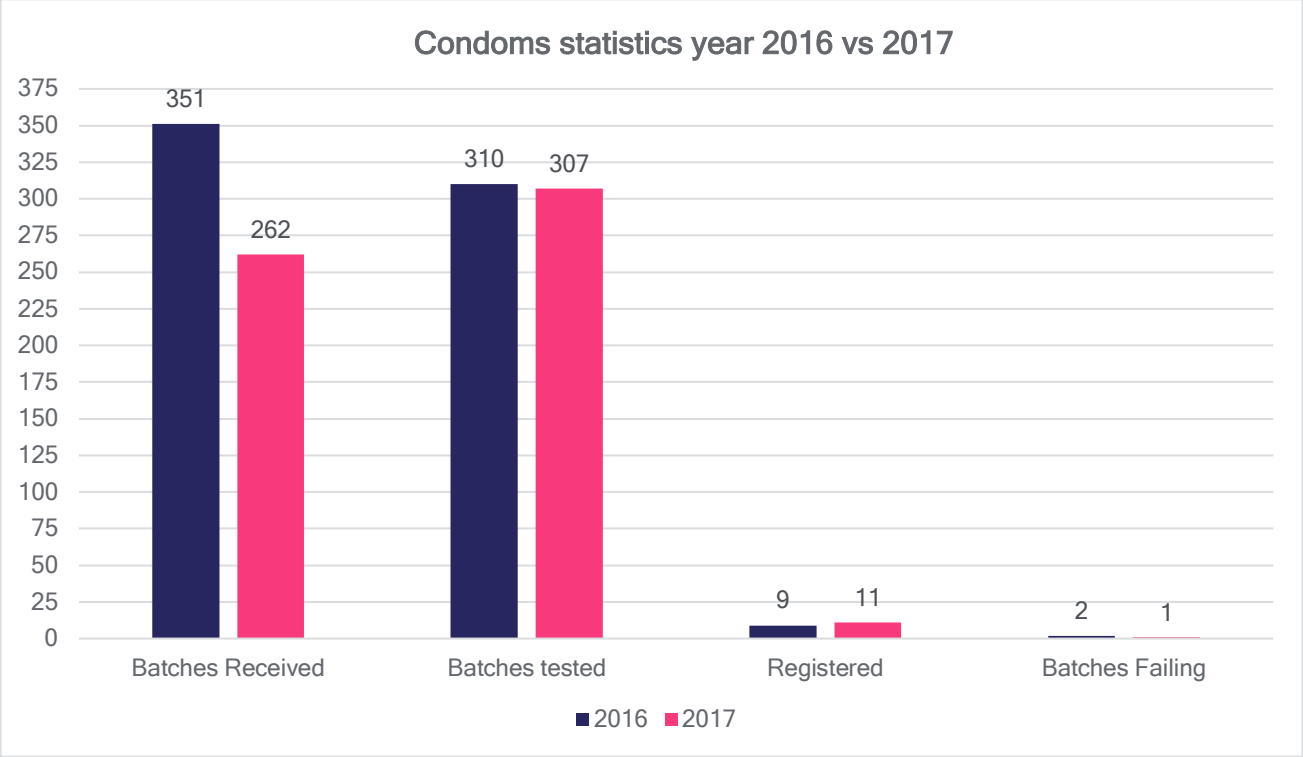


* The discrepancy of forty-five (45) batches is attributed to the carryover of untested samples from year 2016 to 2017 due to the bulk sampling of public sector condom batches

The laboratory received two hundred and sixty-two (262) condom batches for testing in year 2017, and managed to test three hundred and seven (307) batches. There was a 25.36 % decrease in the number of samples received from year 2016 to 2017. This is attributed to logistical delays in receiving the public sector condom batches in the last quarter of year 2017.

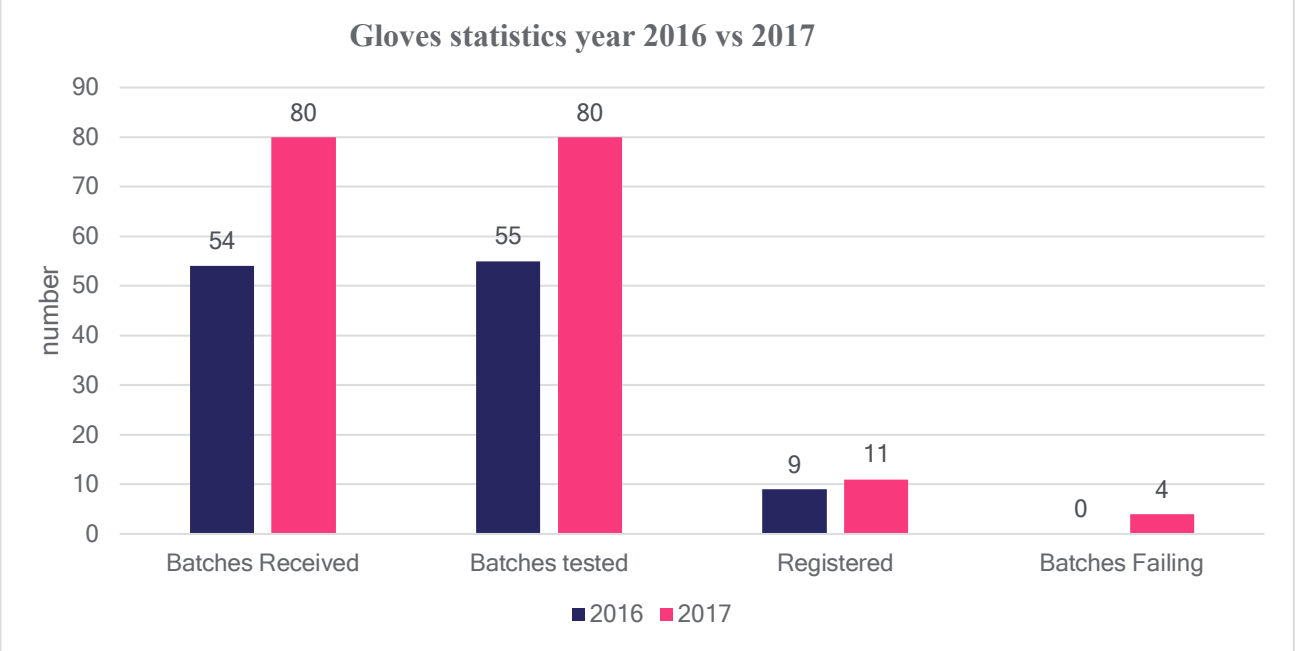
- The laboratory received eleven (11) new condom registration applications, and they were all granted market authorisation.

- One (1) batch of condoms failed quality conformity assessment tests for the period.
- The laboratory continues to participate in annual proficiency testing schemes coordinated by the FHI360 (USA) and Enersol of Australia.



Gloves received and tested

- The laboratory received and tested eighty (80) batches of gloves in year 2017.
- There was a 48.14 % increase in the number of glove batches received from year 2016 to 2017.
- The laboratory received eleven (11) new glove registration applications, and they were all granted market authorisation.
- Four (4) batches of gloves failed quality conformity assessment tests for the period.
- The laboratory continues to participate in annual proficiency testing schemes coordinated by Enersol of Australia.



Quality Unit

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

ISO 17025:2005
ISO 9001: 2015
ISO 17020:2012
WHO prequalification guidelines

The 7 QMS Principles that form the foundation for effective quality management

Highlights

- SADCAS conducted a surveillance audit in March 2017 and the laboratories were recommended for continued accreditation.
- The extension of the scope of accreditation to include the condom lubricant quantity determination test was approved.
- Two Chemistry analysts were deemed competent as technical signatories for UV-Vis spectrophotometry and High Performance Liquid Chromatography (HPLC).