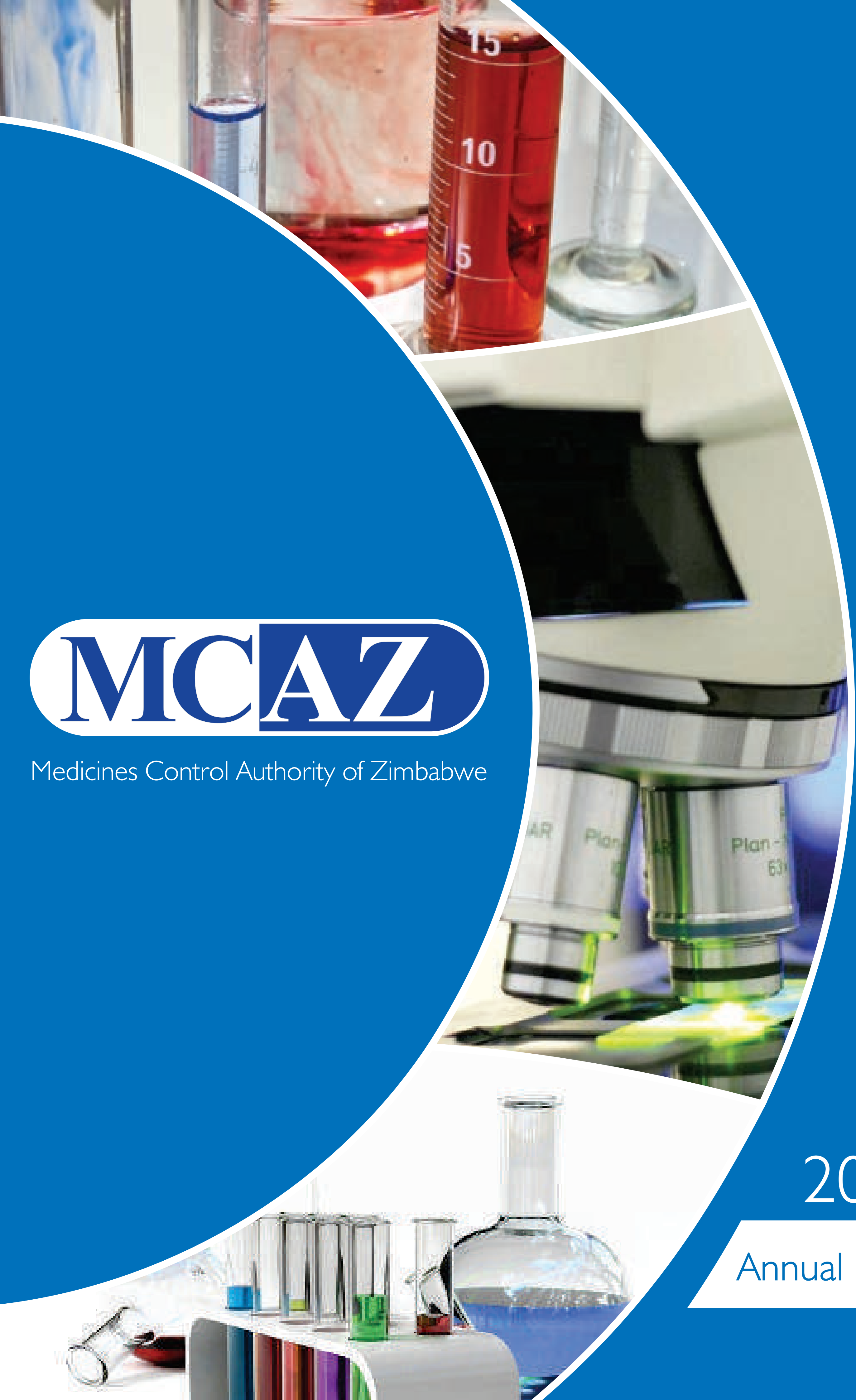

MCAZ

Medicines Control Authority of Zimbabwe

2013 Annual Report

MCAZ
Medicines Control Authority of Zimbabwe

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

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Outlook

MANDATE AND COOPERATE DETAILS

MEDICINES CONTROL AUTHORITY OF ZIMBABWE'S 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.

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CHAIRMAN'S STATEMENT

It is with great pleasure that I present this 2013 Medicines Control Authority of Zimbabwe (MCAZ) Annual Report. The reporting follows the Authority's strategic plan and performance management framework which focuses on the four perspectives of the Balanced Scorecard (BSC): customer, internal business processes, financial performance and learning and growth. It will also provide an overview of the Authority's commitment to people, the planet and productivity.

Customer Perspective

The Authority maintained dialogue with key stakeholders. Quality Circle meetings were held with the Pharmaceutical Manufacturers' Association (PMA) to discuss a roadmap for the adoption of global standards by local manufacturers. Meetings were held with the Pharmaceutical Wholesalers' Association (PWA) and Retail Pharmacists Associations (RPA) to discuss the modalities of ensuring controlled availability of unregistered, yet lifesaving medicines for compassionate use. Meetings were also held with the Division of Veterinary Services (DVS), Council of Veterinary Surgeons (CVSZ) and the Animal Health Industry Committee (AHIC) to ensure controlled access to unregistered life-saving veterinary medicines through licensed outlets.

MCAZ staff made presentations at the Joint Congress of the Pharmaceutical Society and College of Primary Care Physicians. Consumer education was conducted through radio, television and newspaper interviews. In addition, information on correct practices in obtaining and using medicines was electronically disseminated to the public through television displays in supermarkets. This was made possible through the support of the Ministry of Health and Child Care (MoHCC) and its partners in the Health Transition programme. The pinnacle of the Authority's 2013 stakeholder engagement activities was the annual stakeholder's forum held at Rainbow Towers Hotel in Harare to reflect on the achievements of the previous three-years (2011-2013), BSC-based strategic plan and to unveil the new five-year (2014-2018) results based management (RBM) framework strategic plan.

For the internal customers, who are the Authority's employees, the Authority implemented its long service award policy to recognise the loyalty of employees who have stayed with the organisation for five, ten and fifteen years. The Authority also resuscitated the implementation of its Human Resources training and development programme policy to allow employees to pursue approved post-graduate studies in accordance with the learning and growth perspective of the BSC framework.

Internal Business Process

This section provides the highlights of the period under review.

We retained ISO 17025 accreditation status for the Chemistry and Medical Devices laboratories.
The Board (the Authority), through the advice of the Audit Committee, explored the need to rationalise the number and frequency of meetings of the external Expert Committees to ensure efficient and effective oversight of MCAZ functions on behalf of the Board. There were 14 external Expert Committees, the majority of which met monthly and a few every fortnight. In view of the big number and the high frequency of meetings, it was decided to streamline the meetings to allow managers adequate time to execute previous decisions before the following meetings and to conduct preparatory

work for upcoming meetings. It would also allow the external Committee members more time at their own workplaces such as the universities, public health services, and private health sector. Due care was taken to strike a healthy balance between close oversight of operational matters by the Committees and giving management autonomy to execute Board and Committee decisions within the limits prescribed by the statutes, the Board and Committee policies. The changes are being carefully considered to ensure that key responsibilities continue to receive the necessary level of oversight from committees and the Board. The rationalisation process is still ongoing and the Board will periodically review effectiveness.

The Authority also conducted a corporate governance training workshop and developed an evaluation tool for the Board. The Board also re-appointed its legal adviser. The Authority's new Information Communication Technology (ICT) Security and Disaster Recovery Plan (DRP) policies were finalised in 2013 and adopted by the Board. The policies recognise the strategic importance of ICT to the discharge of the MCAZ mandate. The policies reflect the need to protect MCAZ information and applicant intellectual property from cyber threats and provision for business continuity in case of any disasters (earthquakes, infernos, bombing) at the Authority's main premises on Baines Avenue. Mirror servers with automated online real-time backup were installed at secure remote sites.

Financial Perspective

The good financial performance of 2011 and 2012 continued through to December 2013. The sound performance was underpinned by growth in key revenue lines, better follow-up on debts, and good resource mobilisation initiatives. The Authority's pension fund remained solvent and the Authority was able to meet its pension obligations towards its retired employees, at the same time growing the fund for future use by employees in current service.

Learning and Growth

The Authority continued implementation of its performance management using the Balanced Scorecard (BSC). All staff members were appraised in June and in December 2013. Due to the good financial performance of the organization, the Authority managed to pay performance-related bonuses for 2013 in January 2014 to incentivize superior performance. Any gaps in expected performance resulted in the identification of training needs that informed the Authority's training programme.

The Director-General (DG) maintained the quarterly Staff Address meetings to ensure that all staff was aware of the organizational strategic direction and priorities. The sessions also availed a platform for staff to raise any issues they wanted management and the Authority to address.

Corporate Governance and Social Responsibility

The Authority continued to support its pharmacy undergraduate students under the Dr Emilio Simon Mazhindu Scholarship fund that honours the 20-year service rendered by the late and former MCAZ Chairman Dr E. S. Mazhindu in various positions on the MCAZ Board and in Expert Committees. Efforts were to be maintained to reduce our carbon footprint by controlling the amount of waste paper from our various divisions and chemical waste from our laboratories

to ensure that MCAZ remains a responsible corporate citizen that engages in practices that value sustainability and cares for people and the planet, as it carries out its non-profit mandate of safeguarding the health of the Zimbabwe public.

Future Outlook

The Authority is committed to the implementation of the Southern African Development Community (SADC) Harmonisation Programme and elements of the pharmaceutical business plan as well as the African Union's African Medicines Regulatory Harmonisation (AMRH) initiatives. The Authority is indebted to the WHO Prequalification Programme which has greatly informed and improved the training of evaluators and inspectors and our technical competence as a whole. Our gratitude also goes to WHO National Regulatory Strengthening which has scrutinised our regulatory systems and supported our implementation of the Institutional Development Plan. Although Zimbabwe is not a vaccine manufacturing country we have successfully implemented the vaccine lot release programme for all vaccines imported into the country for both the public and private sector. The Authority is also committed to adopting relevant international best practices emanating from WHO, OIE, FAO, ICH and VICH. Our policies and practices reflect the wealth of knowledge acquired from these fora. We wish to the thank all foreign regulatory bodies that accommodated our staff in their international outreach programmes, particularly the USFDA CDER Forum, the Health Canada International Forum, and NPCB international forum.

Mrs J. Ncube
Chairperson

DIRECTOR GENERAL'S STATEMENT

This report reflects on our operations in 2013. It focuses on providing a deeper insight into our operations beyond the usual statements and dry figures. The report complements the Chairman's statement which dwelt more on strategic issues. It is our sincere belief that this report will be informative to all our readers. We are open to your feedback, comments, suggestions and queries.

Customer Perspective

The tenets of good regulatory governance demand that we conduct our regulatory role in a transparent and accountable manner. In 2013 we held several scheduled and special stakeholder consultative meetings to discuss changes in regulatory requirements. In particular, in June 2013, consultations were held with applicants regarding the experiences learnt since the adoption of the CTD-format in August 2012. The Authority lent its ears to the valuable input from industry and availed pertinent information to its customers. For the convenience of our customers that import medicines through the seven of the designated ports of entry where MCAZ has no physical presence, we ensured that the other port officials such as the Zimbabwe Revenue Authority (ZIMRA) and Port Health Authority (PHA) could competently clear conforming consignments in a timely manner. The Authority also maintained its customer feedback and customer complaints systems so that customers could point out system issues that require attention for better and effective service delivery. Our commitment to service excellence enabled us to learn from the feedback and complaints, to improve our system.

Internal Business Process

Under this perspective, we take a deeper look into our operations to gather and interpret data in order to improve our responsiveness and future operational performance.

Human Medicines

The general improvement of the macroeconomic environment since the adoption of the multi-currency regime in 2009 has seen a steady increase in the number of new applications received each year. This increase peaked in 2012 where we recorded 256 new applications. The number for 2013 was 215 new applications, which is still high based on our historical trends from 2009 to 2013. Apart from the correlated increase of numbers of new applications to the recovery of the Zimbabwe economy, the spike in 2012 can also be attributed to industry's reaction to improved turnaround times in 2011 as well as the rush to meet the compulsory requirement for submission of dossiers in the CTD format in the latter part of 2012.

Our performance cannot be measured by inflows without examining the outflow. In 2013 the Authority processed 91 applications, of which 65 (71%) succeeded in getting marketing authorisations and 26 were refused registration for failure to meet the MCAZ CTD guideline requirements. In comparison, in 2012 we had processed a total of 64 applications of which 46 (72%) succeeded in receiving marketing authorisation and 18 were refused registration. Our record performance was in 2011 in which we processed 142 applications of which 84 (59%) were registered and 58 were refused. The year 2011 was a turning point as the screening procedure was introduced then and the number of

and the abridged review of products, were implemented. In addition evaluation retreats are scheduled. The ZaZiBoNa collaboration, a regulatory harmonisation initiative involving Zambia, Zimbabwe, Botswana and Namibia, created a new pathway for review of dossiers submitted to the mutually cooperating countries. It is our belief that the totality of the above interventions and others, will see us clearing the backlog implicit in the above figures.

Veterinary Medicines

The general increase in the numbers of new veterinary applications for registration continued as the Authority recorded 41 applications in 2013 in comparison to the 14 and 20 recorded in 2011 and 2012, respectively. Similar to the trends discussed for human medicines, the numbers of new veterinary applications reflect the better business environment ushered in by the adoption of the multicurrency regime. Credit is also given to the successful adoption by the Authority of the proposal that came from the veterinary industry, led by the Animal Health Industry Committee (AHIC) (an industry body independent of MCAZ structures that represent the local and foreign veterinary pharmaceutical manufacturers), for improving the availability of veterinary medicines.

In 2013 the number of products that received marketing authorisation was 12. The disparity between an inflow of 41 new applications for the year and an outflow of 12 new registrations for the year indicates the levels of deficiencies of the submissions *vis-à-vis* the Zimbabwe CTD guideline that is in use. A number of applications had been reviewed and found not to meet the requirements and the Veterinary Committee agreed to offer applicants more time to generate responses and resolve the gaps identified by assessors. This leniency was given due to the observation that very few veterinary manufacturers had the technical knowledge and financial resources to compile a satisfactory CTD-dossier.

Complementary Medicines

The statistics are given in the section that reports on the activities of the Evaluations and Registration Division. Of interest to our valued stakeholders is the information that the Authority banned male sexual performance enhancing products that claimed to be purely herbal and free of side effects. The ban was precipitated by local and international evidence that these products contained undeclared medicinal substances such as *sildenafil, tadalafil* and *verdanafil* or their analogues, in undisclosed quantities. The spiking agents are known as phosphodiesterase 5 (PD-5) inhibitors which are indicated for the treatment of erectile dysfunction (ED), a medical condition that affects men. Treatment of ED requires patients holding a prescription issued by a medical doctor to obtain registered medicines from licensed pharmacies. The ban was intended to protect consumers who could experience life-threatening side effects if they used the medicines without medical consultations and supervision. The most vulnerable group was men with pre-existing cardiovascular conditions, particularly those taking nitrate antihypertensive drugs.

Licensing of Premises

Our stakeholders are reminded that MCAZ issues annual licences and permits which are renewable every year. This information is key to the interpretation of Licensing and Enforcement statistics. The number of premises licences and permits issued in 2013 closely resemble the 2012 figures. The overall number of licensed pharmacies for 2013 was 434 which is comparable to 445 in 2012. While the overall number appears static, 77 new pharmacies were licensed, some

of these being changes of ownership. Other pharmacies closed shop. A notable increase occurred in the number of licensed industrial clinics from 133 in 2012 to 167 in 2013. This increase is attributable to the recovery of the economy as big manufacturing concerns made provision for basic and emergency medical facilities on site, for their staff. Stabilisation of the economy has also been characterised by a subtle decrease in the number of wholesale dealers from 97 in 2012 to 82 in 2013. This rationalisation is a welcome development as the Authority's role of ensuring the integrity of the medicines distribution channels becomes easier. The ratio of five pharmacies to one wholesale dealer is still too low and remains as evidence of the country's past economic difficulties. The current skewed ratio can also be partly explained by the fact that some wholesale dealers supply institutions that cannot import for themselves. The other reason is that the majority of the 82 wholesale dealers are very small in size thus ballooning the total number of wholesalers while playing an insignificant role in terms of the total volumes traded. Based on sustainability it is anticipated that the number of wholesaler dealers will continue to decrease if the economy remains on the recovery trajectory.

Persons licences

A notable increase in new persons licences issued was recorded for dispensing medical practitioners and dispensing veterinary surgeons, and nurses.

Section 75 Authorisation

Section 75 of the Medicines and Allied Substances Control Act [15:03] makes a provision for the Authority to set aside requirements in the Act to temporarily address legitimate, emergent and unforeseen needs. This provision empowers the Authority to authorise importation of unregistered life-saving medicines on named patient basis, where such patients hold a valid prescription. On rare occasions, the provision has been applied to bulk importation of specified unregistered life-saving medicines in the face of potential disease outbreaks or donations for specific non-profit institutions. The number of section 75 authorisations for importation of prescriptions for individual patients increased from 2 204 in 2011, to 3 736 in 2012 and 6 326 in 2013. Monitoring of these trends allows MCAZ to meet with the Pharmaceutical Wholesalers Association (PWA) and the Retail Pharmacists Association (RPA) to agree on the mechanisms for ensuring controlled availability of the unregistered medicines through designated wholesalers that are authorised to import bulk (pooled) consignments. In cases where the volumes of an individual unregistered medicine reach surrogate business viability thresholds, members of the PWA would liaise with the manufacturer for submission of a registration dossier.

Controlled substances

MCAZ monitors the types, quantities, sources, destination and uses of precursor substances that could potentially be diverted to the manufacture of illicit drugs. Our enforcement of the new legislation pertaining to precursor substances saw a rapid increase from 41 notifications in 2012 to 123 notifications in 2013. This is due to our education campaigns for importers and close collaboration with port control officials. In terms of patient care, health professionals in Zimbabwe still shy away from the provision of narcotic drugs for palliative care. This is evidenced by the low authorisation of 41 permits to import narcotic drugs and frequent distress calls for increased availability of effective pain control options from representatives of palliative care institutions. In the interest of bringing the standard of care for patients that require narcotic analgesics for intractable pain, in line with global standards, better education of prescribers and dispensers is required.

Inspections

Our inspectorate activities for 2013 closely resemble those for 2012.

Pharmacovigilance

The Divisional report contains adequate detail of MCAZ's collaborative effort with Ministry of Health and Child Care (MoHCC) to embed pharmacovigilance in national HIV, TB, and malaria treatment programmes.

Chemistry Laboratory

The details of our operations are in the relevant sections. It is pertinent to mention that the failure rate in quality testing of medicines is less than 5%. This reflects our emphasis on control of supply of medicines from cGMP compliant manufacturers, our document review process and market surveillance in the post-registration period. Our quality testing of bulk imports of antiretroviral drugs is a key contributor to ensuring that the significant number of Zimbabweans living with HIV/AIDs has access to quality assured medication necessary for enhanced and productive quality of life.

Medical Devices Laboratory

The sustained decline in HIV transmission rates in sexually active adults is attributable to the various interventions implemented by the MoHCC and coordination by the National Aids Council (NAC). Our pivotal role in batch-to-batch compliance testing of condoms makes a significant contribution to the declining transmission rates.

Vaccine lot release

Although Zimbabwe is a non-vaccine producing country MCAZ has successfully implemented its Institutional Development Plan (IDP) for strengthening vaccine regulation, including the lot release system, following training received from the WHO National Regulatory System Strengthening.

Financial Perspective

The Chairman's statement pointed out our ability to sustain 80% of our operations from income raised from registration, licensing and retention fees. About 20% of our revenue came from our resource mobilisation initiatives where MCAZ provided valued-added services such as pre-and post-distribution testing of medicines and health commodities for the Ministry of Health and Child Care programmes, supported by development partners such as UNICEF and UNDP.

Learning and Growth

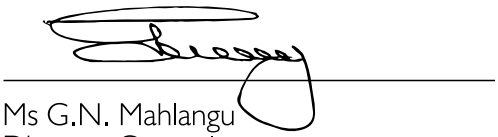
The Authority's Human Resources training and development plan was implemented through in-house training sessions and MCAZ-funded external training. Our assessors continued to benefit through participation at WHO prequalification sessions in Copenhagen and other training opportunities in WHO.

Corporate Governance and Social Responsibility

Our efforts for good corporate citizenry were characterised by our continued contribution to the national manpower and skills development through our scholarships to pharmacy undergraduates and our graduate internship programmes for chemistry, microbiology and ICT graduates.

Future Outlook

At the operational level we are proud of our achievement of successful adoption of the CTD-format for new applications for registration. However, this format has made us grapple with storage space for the huge volumes of files, where one dossier had a record 65 fully packed box files. It is therefore, imperative that we explore e-CTD and better ICT



Ms G.N. Mahlangu
Director-General

GOVERNANCE AND RISK REPORT

The Authority is committed to applying sound corporate governance policies, procedures and practices and application of the requirements set out by the Medicines and Allied Substance Control Act (MASCA) Chapter (15.03), the Public Finance Management Act (PFMA) Chapter (22.19), The King Code on Corporate Governance for Southern Africa 2009 (King III), the Corporate Governance Framework (CGF) for State Enterprises and Parastatals that was adopted by the Government of Zimbabwe (GoZ) in November 2010, and the International Financial Reporting Standards (IFRS) among notable laws, rules, regulations, guidelines and standards in practising good corporate governance and financial accounting practice.

The Authority believes that corporate governance is core to ensuring the creation, protection and enhancement of stakeholder value. Our stakeholders include the Government of Zimbabwe, the MoHCC and other Government Ministries, Parastatals and State Enterprises, the pharmaceutical and health industries, the public at large and our suppliers.

The Authority is required by the MASCA, PFMA and the CGF to produce annual audited financial statements. The Authority has managed to produce audited financial statements over the years. The 30 June deadline to produce the statements however remains a challenge.

This statement outlines the main corporate governance practices of the Authority that are in place.

The Board of Directors

The Board, is accountable to and is appointed by the Minister of the MoHCC in terms of section 4 of the MASCA with the aim of providing it with a mixture of different skills and expertise to enhance debate and proper guidance of the Authority's operations. All members of the Board are non- executive.

The Director-General (DG) who is the Chief Executive Officer of the Authority is the head of the Secretariat. The Board meets at least quarterly every year. At any given time the Board should consist of not less than eight and not more than twelve members as determined by the Minister subject to subsection (2) of section 4 of the MASCA.

The Board is responsible for setting and reviewing the strategic direction of the MCAZ and the implementation of that strategy by management, including:

- Promoting ethical and responsible decision-making
- Monitoring compliance with all relevant laws, rules, regulations, applicable accounting standards and significant corporate policies.
- Overseeing of the organization, including its governance, risk management and control and frameworks.
- Approving the annual strategic and operational plans and monitoring the performance of the organization.
- Approving the annual financial budget and monitoring of the same.
- Monitoring the performance of the CEO and management.
- Ensuring that stakeholders are fully informed of material developments

The DG 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.

As a matter of principle every member of the Board or its Committees is required to declare any interest before the commencement of meetings. Any such members who declare their interests are expected to recuse themselves from any deliberations made related to the interests declared.

As at 31 December 2013, the composition of the Board was as follows;

MEMBER	SECTION UNDER WHICH APPOINTMENT IS MADE	DATE APPOINTED	TERMINATION
Mrs J. Ncube (Chairperson)	Section 4(2) (e) (Law Society)	31 July 2011	31 March 2014
Dr. A. F. Zinanga (Vice Chairman)	Section 4(2) (a) (Medical Association)	01 April 2011	31 March 2014
Dr. P Muvavarirwa	Section 4(2) (b) (Council of Vet. Surgeons)	01 April 2011	31 March 2014
Mrs J. Chaibva	Section)4(2) (c) (Pharmaceutical Society	31 August 2011	31 March 2014
Dr. P Chonzi	Section 4(2) (d) (Local Authority)	31 July 2011	31 March 2014
Dr. R. Gwisai	Section 4 (2) (f) (Specialist Physician)	31 July2011	31 March 2014
Dr. T. R. Bwakura	Section 4(2) (g) (knowledge of action & application of medicines)	01 April 2011	31 March 2014
Mrs R. Hove	Section 4(2) (h) (Ministry of Health)	28 July 2011	31 March 2014
Dr. C.C Maponga	Section 4(1) (Any other)	01 April 2011	31 March 2014
Mrs. F.N. Sifeku	Section 4(1) (Any other)	01 April 2011	31 March 2014
Mrs. D. Mandaza	Legal Adviser	----------	----------

Board Committees

In line with good governance, Board Committees have been established to assist the Board in the discharge of its responsibilities. Individuals with specific qualifications and experience, who are not part of the Board, are incorporated into the Board Committees to provide diversity and add depth to the quality of Committee debates. The Board Committees are guided by specific approved terms of reference. The Committees are accountable to the Board, with their minutes circulated and reported on at the subsequent Board meeting.

All of the Board Committees are chaired by a member of the Board. Members of the management team are invited to attend meetings as appropriate.

The following Board Committees have been established:

Audit Committee

The Board has an Audit Committee which is responsible for assisting the Board in fulfilling its corporate governance responsibilities in relation to:

- The integrity of financial reporting
- Compliance with applicable laws, rules and regulations
- The effectiveness of the enterprise - wide governance, risk management and internal control framework
- Oversight of the internal audit function
- Oversight of the external auditors

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. To this end, the Human Resources Committee was established in 2011 and some of its primary functions are to review the formulation 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 Committee which helps the Authority achieve this is the Finance Committee, which sits quarterly to review the management accounts. This Committee also assists the Board in ensuring that financial resources are budgeted, and utilized prudently and in the most effective and efficient manner, contributing towards the organisation's overall mission, objectives and strategies.

BOARD AND COMMITTEE ATTENDANCE
(FROM 1 JANUARY 2013 TO 31 DECEMBER 2013)

NAME OF MEMBER	BOARD		AUDIT COMMITTEE		HR COMMITTEE		FINANCE COMMITTEE	
	ATTENDED	POSSIBLE	ATTENDED	POSSIBLE	ATTENDED	POSSIBLE	ATTENDED	POSSIBLE
Mrs. J. Ncube	4	4			6	8		
Dr. A. F. Zinanga	4	4					10	11
Dr. P Muvavarirwa	4	4	6	6	7	8	10	11
Mrs J. Chaibva	4	4	5	6				
Dr. P. Chonzi	3	4	3	6	3	8		
Dr. R. Gwisai	3	4			7	8		
Dr. T. R. Bwakura	2	4						
Mrs. R. Hove	1	4						
Dr. C.C. Maponga	3	4			6	8	8	11
Mrs. F.N. Sifeku	2	4	4	6	7	8		
Mrs. D. Mandaza	3	4	4	6				
Mr. C. F. Dube								
Mr. F. Gwiza								
Mr. E. Jinda					8	8		
Mr. J.B. Nderere							6	11
Mr. E.C. Mbodza							11	11

Overall the Board attendance rate was satisfactory and in sufficient numbers to form a quorum. This also ensured that there was sufficient debate 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.

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
Mr P. N. Ndanga	Quality Manager
Mr T. Gonho	Manager- Medical Devices and Micro- Biology
Mr T. Munhenga	Human Resources Manager (From 01 February 2013)
Mrs M.A. Maunga	Legal Manager
Ms S. Buwu	Head of Internal Audit Unit (to 30 November 2013)
Mr H Ngwarai	Head of Internal Audit Unit (from 06 January 2014)
Mrs A.T. Moyo	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 main Board in compliance with the ERM Framework.

Internal Audit

The internal audit function is carried out by the Internal Audit Unit. The Unit has 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 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 and risks facing the organization.

The audit plan and work plans are approved by the Audit Committee annually.

Corporate Social Investment (CSI)

The Authority is a socially responsive organisation which strives to give back to the community in which it operates. Pursuant to this objective it has a provision for sponsoring third and fourth year Pharmacy undergraduates from the University of Zimbabwe. This generous gesture has been honoured since 2007. Three scholarships are available annually. In addition to the scholarship programme, the Authority also offers pre-registration pharmacists the opportunity for community service while gaining the required industrial experience in fulfilment of their degree program. During the course of 2013 the Authority sponsored three undergraduate students under the scheme - two in their third year and one in the fourth and final year. The individual who was in the final year has since graduated and is currently undertaking the final part of the pre-registration training with the Authority. The Authority also has a two year Graduate internship program. During the year the Authority recruited five graduate interns, two in the Chemistry Division and one each in the Microbiology and Medical Devices, Quality and ICT Units. Subject to availability of vacancies some of these graduates may be offered job opportunities within the Authority.

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 31, 2013.

Report on the Financial Statements

I have audited the accompanying financial statements of Medicines Control Authority of Zimbabwe, which comprise the statement of financial position as at December 31, 2013 and the statement of profit or loss and other comprehensive income, the statement of changes in equity and statement of cash flows for the year then ended, and the notes to the financial statements, which include a summary of significant accounting policies and other explanatory notes as set out on pages 20-34.

Director's Responsibility for the Financial Statements

The Authority's management is responsible for the preparation and fair presentation of these financial statements in accordance with International Financial Reporting Standards (IFRS) and in the manner required by the Medicines and Allied Substances Control Act [Chapter 15:03]. 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 financial statements based on my audit. I conducted my audit in accordance with the International Standards on Auditing. Those Standards require that I comply with ethical requirements and plan and perform the audit to obtain reasonable assurance as to whether or not the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Authority's preparation and fair presentation of the 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 Authority'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 financial statements.

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

Opinion

In my opinion, the financial statements present fairly, in all material respects, the financial position of Medicines Control Authority of Zimbabwe as at December 31, 2013, 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 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 relevant Statutory Instruments.

OCTOBER 17 , 2014

M. Chiri
Auditor - General

STATEMENT OF FINANCIAL POSITION
as at December 31, 2013

	Note	Historical Cost 2013 US$	Historical Cost 2012 US$
ASSETS			
Non-Current Assets		**4,864,022**	**4,481,913**
Property, plant and equipment	4	2,872,772	2,832,318
Investment properties	5	1,391,250	1,431,000
Available for sale investments		600,000	218,595
Current Assets		**996,207**	**962,264**
Inventories	6	36,163	37,921
Trade receivables		248,163	165,271
Other receivables	7	204,375	108,046
Prepayments		12,924	100
Cash and cash equivalents	8	494,583	650,926
Total Assets		**5,860,228**	**5,444,177**
RESERVES AND LIABILITIES			
Reserves		**5,080,575**	**4,728,618**
Capital Reserve		5,234,444	5,234,444
Retained Earnings		(535,273)	(505,826)
Revaluation surplus		381,404	-
		380,749	**248,079**
Deferred income	9	380,749	248,079
Current Liabilities		**398,904**	**467,480**
Trade payables		16,038	49,611
Other payables	10	307,938	356,530
Leave pay provision		74,928	61,339
Total Reserves and Liabilities		**5,860,228**	**5,444,177**

Mrs J. Ncube
Chairperson - 2014

Ms G.N.Mahlangu
Director-General - 2014

STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME for the year ended December 31 2013

	Note	Historical Cost	
		2013 US$	2012 US$
INCOME		**3,570,771**	**3,125,582**
Deferred income	9	48,129	30,748
Investment interest income	11	156,060	116,990
Medicines control income	12	2,623,627	2,491,615
Laboratory services	13	256,540	186,665
Donations		441,902	249,135
Profit on disposal of property, plant and equipment		2,707	4,418
Other Income		41,807	46,011
EXPENDITURE		**3,600,218**	**2,997,263**
Employment costs	14	2,014,278	1,596,051
Administration Expenses	15	1,585,940	1,401,212
(Deficit)/Surplus for the year		**(29,447)**	**128,319**
Other Comprehensive Income			
Revaluation surplus		381,404	-
Total comprehensive income		**351,957**	**128,319**

STATEMENT OF CHANGES IN RESERVES
for the year ended December 31 2013

	Revaluation Reserve US$	Retained Earning US$	Capital Reserve US$	Total US$
Balance as at January 01, 2012	-	(634,145)	5,234,444	4,600,299
Total Comprehensive Income for the year	-	128,319	-	128,319
Balance at December 31, 2012	-	(505,826)	5,234,444	4,728,618
Deficit for the year	-	(29,447)	-	(29,447)
Revaluation surplus for the year	381,404	-	-	-
Balance as at December 31,2013	381,404	(535,273)	5,234,444	5,080,575

STATEMENT OF CASH FLOWS
for the year ended December 31, 2013

	Note	Historical Cost	
		2013 US$	2012 US$
Net Cash flow from Operating Activities		(21,751)	477,244
Surplus/(Deficit) for the year		(29,447)	128,319
Adjusted for non cash items:		280,148	238, 181
Depreciation	4&5	346,361	313,325
(Decrease) / Increase in provision for leave pay		13,589	(26,930)
Deferred income	9	(48,129)	(30,748)
Loss / (Profit) on disposal of property, plant and equipment		(2,707)	(4,418)
Interest earned		(28,966)	(13,048)
Working capital changes:		(272,451)	(110,744)
Increase in inventory		1,758	(22,330)
Increase in trade receivables		(82,892)	(17,680)
Decrease / (Increase) in other receivables		(96,328)	16,491
Increase in prepayments		(12,824)	3,168
(Decrease)/Increase in payables		(33,573)	36,182
Increase in other payables		(48,593)	94,913
Net Cash Flow from Investing Activities:		(134,593)	(166,577)
Purchase of property, plant and equipment		(167,430)	(209,018)
Proceeds from Disposal of property, plant and equipment		3,871	29,393
Interest received		28,966	13,048
Net Increase/decrease in cash and cash equivalents		(156,343)	310,667
Cash and Cash Equivalents at beginning of the year		650,926	340,259
Cash and Cash Equivalents at year end	8	494,583	650,926

NOTES TO THE FINANCIAL STATEMENTS
For the year ended December 31, 2013.

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 the 1st of August 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 Statement of compliance

The financial statements for the year ended December 31, 2013, have been prepared in conformity with International Financial Reporting Standards, promulgated by the International Accounting Standard Board (IASB), which includes standards and interpretations approved by the IASB as well as International Accounting Standards and Standing Interpretations Committee.

2.2 Basis of measurement

The financial statements are based on the statutory records that are maintained under the historical cost basis, or deemed cost at revaluation at conversion to US dollar currency in 2009, 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 revalued amounts;

2.3 Functional and presentation currency

These financial statements are presented in United States Dollar (US$) which is the Authority'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 Authority 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 and revised standards and interpretations

2.5.1. Adopted new standards, interpretations and amendments effective from January 1, 2013.

The adoption of the standard or interpretation is described below:

i. IFRS 9 Financial Instruments: Classification and measurement

IFRS 9, as issued, reflects the first phase of the IASB's work on the replacement of IAS 39 and applies to classification and measurement of financial assets and financial liabilities as defined in IAS 39. In subsequent phases, the IASB will address hedge accounting and impairment of financial assets. The adoption of the first phase of IFRS 9 will have an effect on classification and measurement of the Authority's financial assets, but will potentially have no impact on classification and measurement of financial liabilities. This standard became effective for annual periods beginning on or after January 1, 2013.

ii. IFRS 13 Fair value measurement

IFRS 13 establishes a single source of guidance under IFRS for all fair value measurements. IFRS 13 does not change when an entity is required to use fair value, but rather provides guidance on how to measure fair value under IFRS when fair value is required or permitted. This standard became effective for accounting periods beginning on or after January1, 2013.

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, 2012.

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 Authority 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.

The rates that were applied per annum are as follows:

Items	Rate
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 decease for the same asset previously recognized in profit and loss, in which case the increase is credited to profit and 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 measured under the cost model.

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.

Any gains or loss on disposal of an investment property is recognised in profit or loss. When an investment property that was previously classified as property, plant and equipment is sold, any related amount included in the revaluation reserve is transferred to retained earnings/accumulated fund.

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.

They exclude those forms of government assistance which cannot reasonably have value placed upon them and transactions with government which cannot be distinguished from the normal trading activities.

Grants related to income are credited to the statement of comprehensive income as revenue grants.

Non-monetary grants are valued at nominal amounts based on management estimates.

3.3 Taxation

The Authority is exempt 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 Authority's statement of financial position when the Authority becomes 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 Authority 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 Authority 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 and 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 Authority on terms that the Authority 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.

3.4.2 Financial liabilities

3.4.2.1 Liabilities and provisions

Provisions are recognized when the Authority 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. Liabilities payable after one year from the reporting date are treated as non-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 Authority 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 Authority 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.

The Authority ceded 41% of Pandora House into the Pension Fund to boost its value. This arrangement was effective January 2011.

In addition, the Authority also contributes to the National Social Security Authority Scheme which was promulgated under the National Social Security Authority Act, (Chapter 17:04) of 1989. The Authority's obligations under the scheme are limited to specific contributions as legislated from time to time.

NOTES TO THE FINANCIAL STATEMENTS
For the year ended December 31, 2013.

4. PROPERTY, PLANT AND EQUIPMENT

	Land & Buildings US$	Plant & Machinery US$	Motor Vehicles US$	Computers & Equipment US$	Office Equipment US$	Furnitures & Fittings US$	Total 2013 US$	Total 2012 US$
Opening Carrying Amount	**1,614,352**	**899,697**	**179,918**	**50,571**	**18,541**	**69,239**	**2,832,318**	**2,728,880**
Cost	1,793,600	1,374,846	362,984	123,055	46,367	99,338	3,800,190	3,480,607
Accumulated Depreciation	(179,248)	(475,149)	(183,066)	(72,484)	(27,826)	(30,099)	(967,872)	(751,727)
Additions	-	13,018	80,725	32,877	7,490	33,320	167,430	209,018
Donations	-	20,685	74,600	78,286	7,228	-	180,799	192,970
Carrying amount on disposals	-	-	(1,164)	-	-	-	(1,164)	(24,975)
Disposal's	-	-	(13,337)	-	-	-	(13,337)	(82,405)
Depreciation on disposals	-	-	12,173	-	-	-	12,173	57,430
Depreciation for the year	(44,840)	(139,247)	(74,479)	(28,893)	(8,567)	(10,585)	(306,611)	(273,575)
Closing Carrying Amount	**1,569,512**	**794,153**	**259,600**	**132,841**	**24,692**	**91,974**	**2,872,772**	**2,832,318**
Cost	1,793,600	1,408,549	504,972	234,218	61,085	132,658	4,135,082	3,800,190
Accumulated Depreciation	(224,088)	(614,396)	(245,372)	(101,377)	(36,393)	(40,684)	(1,262,310)	(967,872)

NOTES TO THE FINANCIAL STATEMENTS
for the year ended December 31, 2013.

		Note	Historical Cost	
			2013	2012
5	**Investment property**		**US$**	**US$**
	Adjusted Opening Carrying Amount		**1,431,000**	**1,470,750**
	Deemed Cost		1,590,000	1,590,000
	Accumulated Depreciation		(159,000)	(119,250)
	Depreciation for the year		(39,750)	(39,750)
	Closing carrying amount		**1,391,250**	**1,431,000**
	Cost		1,590,000	1,590,000
	Accumulated Depreciation		(198,750)	(159,000)
6	**Inventories**			
	Fuel		20,034	29,171
	Provisions		4,414	-
	Stationery consumables		11,715	8,750
			36,163	**37,921**
7	**Other receivables**			
	Rentals		32,362	32,762
	Staff receivables		98,148	1,784
	Sundry receivables		73,865	73,500
			204,375	**108,046**
8	**Cash and Cash equivalents**			
	Cash and bank		219,923	446,285
	Funds on placement		274,660	204,641
			494,583	**650,926**
9	**Deferred income**			
	Opening carrying amount		248,079	85,857
	Additions of donated equipment		180,799	192,970
	Amortisation for the year		(48,129)	(30,748)
	Closing carrying amount		**380,749**	**248,079**

NOTES TO THE FINANCIAL STATEMENTS
for the year ended December 31, 2013.

		Historical Cost	
		2013	2012
		US$	US$
10	**Other payables**		
	Audit fees	15,700	23,400
	Sundry payables	251,819	297,921
	Unallocated income	40,419	35,209
		307,938	**356,530**
11	**Investment income**		
	Interest earned	28,966	13,048
	Rentals	127,094	103,942
		156,060	**116,990**
12	**Medicines control income**		
	Amendment Fees	63,707	63,087
	Clinical Trials	21,200	12,500
	Dangerous Drug License	9,313	5,740
	Drug registration and forensic Examination	22,128	21,000
	Import and Export Licenses	220,641	203,472
	Inspection	173,693	175,617
	Other Income	31,379	6,302
	Persons and Premises Licenses	151,405	105,040
	Registration Fees	620,915	655,960
	Renewal of Licenses	311,794	250,500
	Retention Fees	694,068	683,471
	Sales representatives and Wholesale Dealers	163,665	209,186
	Training Medicines	400	16,000
	Unregistered Medicines	104,809	60,590
	Veterinary Permits	34,510	23,150
		2,623,627	**2,491,615**

NOTES TO THE FINANCIAL STATEMENTS
for the year ended December 31, 2013.

		Historical Cost	
		2013	2012
		US$	US$
13	**Laboratory services Income**		
	Condom Testing	101,570	91,280
	Glove Testing	16,700	6,575
	Medical Devices-Registration	3,750	7,500
	Samples-External Clients	134,520	81,310
		256,540	**186,665**
14	**Employment costs**		
	Pension and Medical Aid	234,526	199,301
	Salaries and Wages	1,563,880	1,277,352
	Staff Recruitment	9,972	12,864
	Staff Training Expenses	13,063	12,794
	Staff Welfare	18,034	16,018
		1,839,475	**1,518,329**
	Compensation for key management		
	Board members benefits	10,248	16,480
	Board members fees	92,459	61,242
	Director General benefits	19,200	-
	Director General salary	52,896	-
		174,803	**77,722**
	Total employment costs	**2,014,278**	**1,596,051**

NOTES TO THE FINANCIAL STATEMENTS
for the year ended December 31, 2013.

		Historical Cost	
		2013	2012
		US$	US$
15	Administration expenses		
	Audit fees	12,000	10,900
	Bank charges	17,103	13,609
	Communications	47,040	57,825
	Consumables	32,186	58,979
	Credit loss	-	11,025
	Depreciation	346,361	313,325
	Fines	-	162
	General administration	38,112	30,167
	Inspections	146,540	121,722
	Investment properties	129,141	146,746
	IT expenses	103,964	69,666
	Legal and Professional fees	47,578	58,225
	Printing and Stationery	118,198	82,048
	Provision for Doubtful Debts	3,550	-
	Provision for leave pay	13,589	-
	Public relations	19,118	6,486
	Quality assurance costs	8,345	15,572
	Rates, Electricity and Water	19,178	17,560
	Repairs and Maintenance	118,810	60,363
	Security and Insurance costs	34,501	18,321
	Strategic planning	129,733	64,071
	Subscriptions	13,383	10,144
	Travelling and Subsistence	28,958	60,756
	Vehicle running costs	142,901	152,692
	Directors expenses	15,651	20,848
		1,585,940	1,401,212

EVALUATIONS AND REGISTRATIONS

HUMAN MEDICINES

Applicants wishing to register human medicines in Zimbabwe must submit documentation regarding safety, efficacy and quality of the medicine in the formats prescribed by the Medicines and Allied Substances Control Act [Chapter 15:03], the Medicines and Allied Substances Control (General) Regulations, 1991 (SI 150 of 1991) and the guidance in the MCAZ Common Technical Document (CTD) Registration Guideline which incorporates principles from the SADC Harmonisation Registration Guidelines and the World Health Organisation (WHO) Prequalification CTD 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 Harmonisation (ICH).

The documentation is then evaluated to establish compliance with the above scientific and administrative registration requirements, as well as the policies set by the Registration Committee over the years. Evaluation is conducted in-house by qualified, trained, skilled and competent officers. Oversight and final approval of the medicines is granted by the Registration Committee comprised of external experts appointed by the MCAZ Board in consultation with the Minister of Health and Child Care.

Activities

- In 2013, two hundred and fifteen (215) new applications for registration were received. Of these, thirty nine (39) were new chemical entities and one hundred and seventy-six (176) were generic applications.
- A total of sixty two (62) applications were registered in 2013 a figure higher than the number of products registered in the years 2011 and 2012. Of the registered products sixteen (16) were anti-viral medicines, three (3) were anti-malarial medicines, four (4) were anti-convulsants, four (4) were antibiotics, seven (7) were anti-hypertensive medicines and twenty-eight (28) were other medicines that fell into various classes. In addition twenty six (26) applications were refused registration due to failure to address registration requirements, whilst twelve (12) previously cancelled applications were re-instated. The register of approved human and veterinary medicines is now available on the MCAZ website.
- The Authority began to accept applications under the Expedited Review Procedure in August 2013 after a consultative meeting was held with stakeholders in June 2013. This procedure ensures that products are registered in a shorter time, improving access on to the market. The procedure is applicable to all applications with shorter timelines for products that are WHO pre-qualified or approved in stringent regulatory authorities.
- The Authority participated in a voluntary, work-sharing arrangement among mutually cooperating countries: Zambia, Zimbabwe, Botswana and Namibia. The programme is now popularly known by its acronym, ZaZiBoNa depicting names of the mutually cooperating countries. Two meetings were held in 2013 and 10 products were evaluated. Products that were considered during the two meetings were anti-retrovirals, anti-cancer products, anti-epileptic drugs and contraceptives. This collaboration fosters harmonisation among the mutually cooperating countries and will result in improved access to medicines in the four (4) countries.

Comparison Of Human Medicines Processed in 2012 and 2013

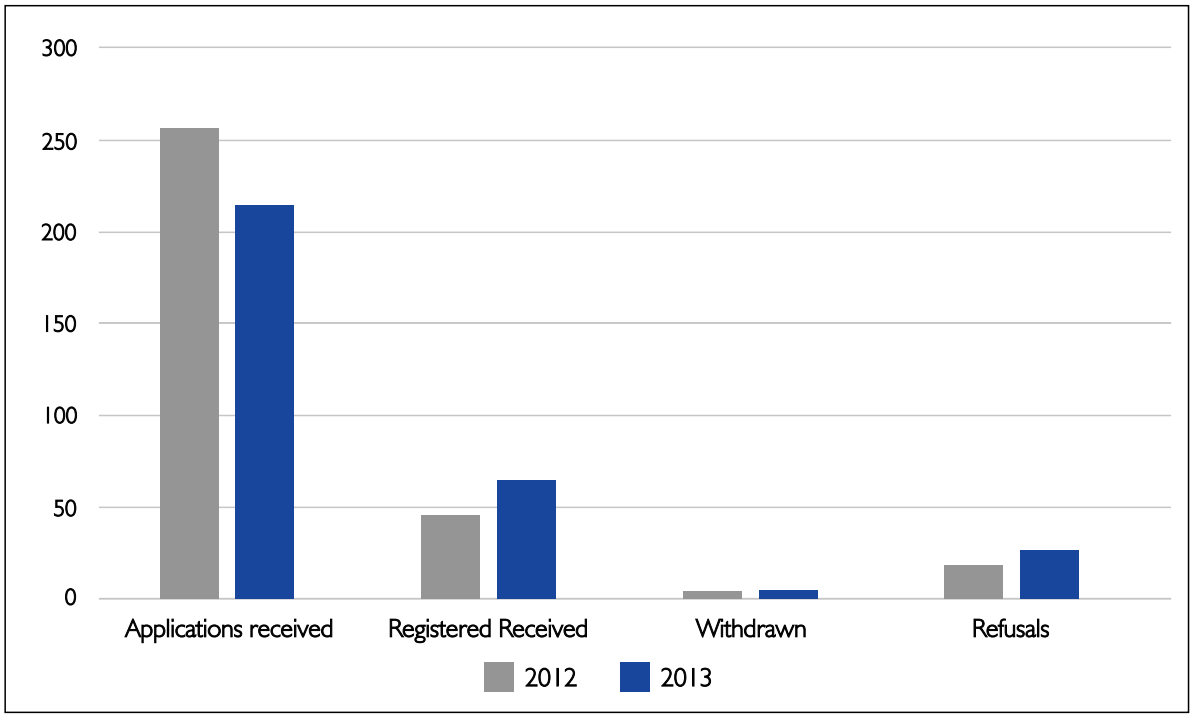


Figure 1: Human Medicines Processed between 2012-2013 (*Source:* MCAZ Evaluations and Registrations December, 2013)

Comparison of Pharmacological classes of medicines registered in 2012 and 2013

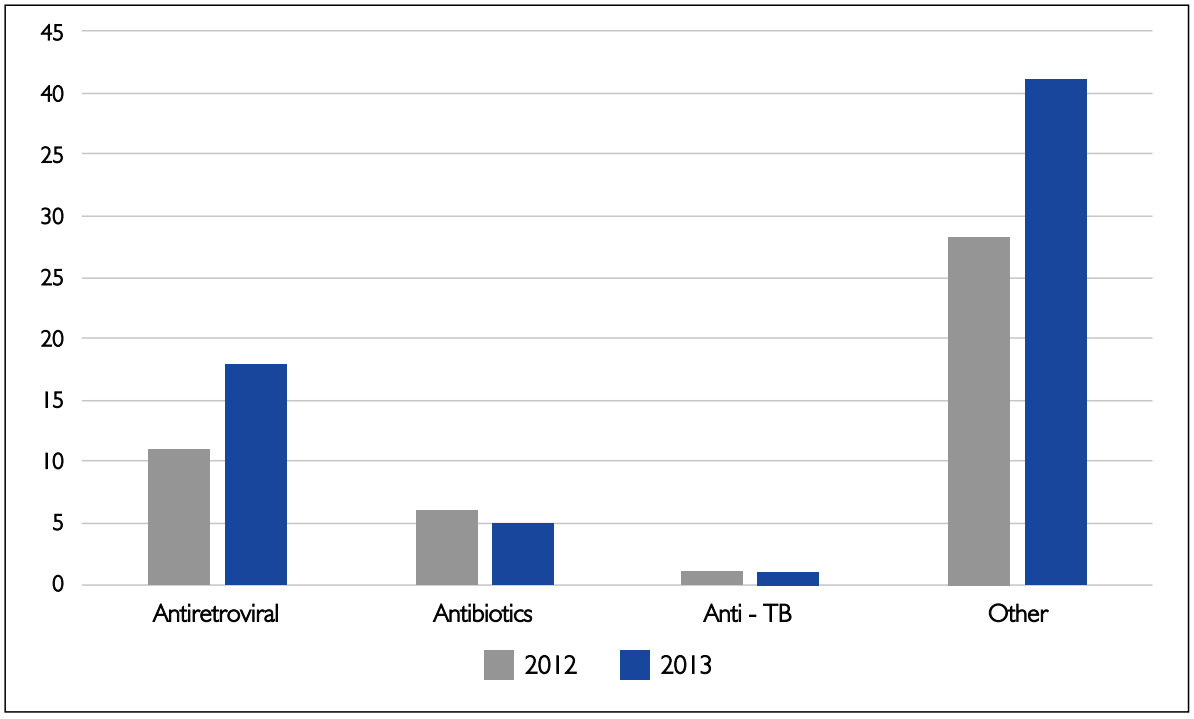


Figure 2: Medicines Registered by MCAZ from 2012 - 2013, by Class (*Source:* MCAZ Evaluations and Registrations December 2013)

VETERINARY MEDICINES

Similar to that for the registration of human medicines is carried out for the registration of veterinary medicines. Applicants wishing to register veterinary medicines in Zimbabwe have to submit documentation regarding safety, efficacy and quality of the medicine in the formats prescribed by the Medicines and Allied Substances Control Act [Chapter 15:03], the Medicines and Allied Substances Control (General) Regulations, 1991 (SI 150 of 1991) and the guidance in the MCAZ Common Technical Document (CTD) Registration Guideline which incorporates principles from the SADC Harmonisation Technical Requirements for Registration of Veterinary Medicines Guidelines, the World Organisation for Animal Health (Office International de Epizooties) [OIE] and the International Conference on Harmonisation of Technical Requirements for Registration of Veterinary Medicines (VICH) 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 registration requirements, applicants wishing to register acaricides (dip chemicals) for control of ticks have to submit applications for conducting local (in country) dipping trials co-approved by MCAZ and the Division of Veterinary Services (DVS). The joint approval ensures the choice of the appropriate dipping trial sites, one in the high veld and another in the low veld; 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 monitors adherence to animal welfare standards prescribed by the Animal Health Act [19:02]. The DVS through its specialist Dipping Committee, monitors trial sites to ensure proper conduct of the trial and verifies the correct execution of half body tick counts on dipped and undipped control animals in accordance with the Dipping Guidelines. The peak tick activity coincides with the peak rainy season in Zimbabwe (November to March), therefore the Veterinary Committee in consultation with the DVS Dipping Committee resolved that applications for any dipping trials to commence at the beginning of the current year's rainy season (November) to the end of the rainy season in the following year (March), must be received at MCAZ and DVS before the 31st October of the current year. Any applications for conducting clinical trials received after the cut-off date may be evaluated, but the trials will not be approved for commencement in the current rainy season.

The documentation submitted to support applications for registration is evaluated to establish compliance with the above scientific and administrative registration requirements, as well as the policies set by the Veterinary Committee over the years. Evaluation is conducted in-house by qualified, trained, skilled and competent officers. Oversight and final approval of the medicines is granted by the Veterinary Committee comprised of external experts appointed by the MCAZ Board in consultation with the Minister of Health and Child Care. Amongst the veterinary expert committee members, a quota is reserved for veterinarians from the Government Division of Veterinary Services.

Activities

- In 2013, forty one (41) applications for registration of veterinary medicines were received.
- Twelve (12) applications were registered, while one (1) application was withdrawn from the evaluation process by the applicant and one (1) product was cancelled.
- The Authority developed a draft CTD Guideline for Registration of Veterinary Medicines in 2013 based on SADC Harmonisation on Technical Requirements for Registration of Veterinary Medicines and VICH guidelines. The guideline was circulated to Industry for comments and is nearing finalisation.

Comparison of Veterinary Medicines Processed in 2012 and 2013

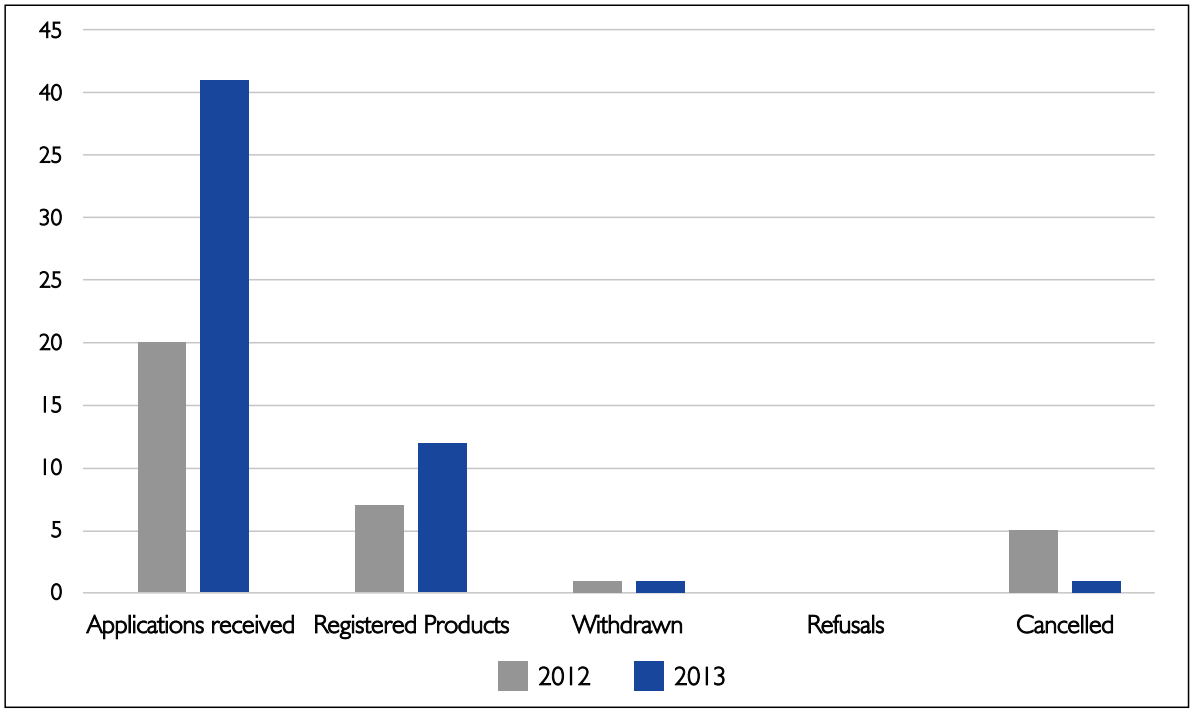


Figure 3: Veterinary Medicines Processed At MCAZ between 2012-2013 (*Source:* MCAZ Evaluations and Registrations December, 2013)

COMPLEMENTARY AND HERBAL MEDICINAL PRODUCTS

Broadly, these are herbal medicines or preparations consisting solely of plant substances. Complementary medicines include homeopathic, anthroposophic and Asian medicinal products. A distinction is made between those medicinal products with and those without medicinal claims. A greatly simplified process that assures quality in all cases is in place to assess the requirement for registration. Current measures include bioburden testing of oral preparations to confirm absence of pathogenic bacteria such as *Staphylococcus aureus*, *salmonella spps*, *E. coli spps* and other enterobacteriacae. The other quality test, yet to be implemented, is the heavy metals test by atomic absorption spectrum to rule out the presence of toxic heavy metals such as lead and arsenic.

The foregoing discussion states the interim measures currently being employed. A more holistic and yet simplified registration process for complementary medicines is in the pipeline. The Authority is awaiting approval of the complementary medicines regulations by the Minister of Health and Child Care in order to begin registering complementary medicines. The registration process will require risk-based GMP inspection of the manufacturing facility, evaluation of an abridged dossier and testing of product samples to deter from the market poor quality, unsafe and potentially ineffective complementary medicines while allowing good quality, safe and potentially effective complementary medicines that aid healthy lifestyles, prevention of disease conditions and support treatment.

In 2013, the MCAZ banned herbal male sexual performance enhancing agents due to the high incidences of spiking of these preparations with phosphodiesterase 5 (PDE-5) inhibitors and their analogues. While the products had gained popularity on the market with men wishing to 'boost their stamina', the risk of serious cardiovascular side effects in the absence of medical advice and supervision far outweighed the social benefits of using such medicines. Although the ban may have created a black market for the commodity, the ban presented an opportunity for the public to learn about the dangers of using the products without medical supervision. The ban regularised the anomaly where registered male erectile dysfunction medicines were available only on prescription yet the herbal counterfeits or substitutes, most with a strong possibility of being spiked with chemical drugs, were available over-the-counter after evading registration by masquerading as health supplements for men.

Activities

- In 2013, there were one hundred and eight (108) applications for determination of whether or not the herbal and complementary medicinal products submitted required registration. The applications were presented to the Registration Committee.
- Ninety three (93) were confirmed to require registration on account of either making medicinal claims or containing medicinal ingredients. The applicants were advised to follow normal registration procedures.
- Fifteen (15) were confirmed to not require registration and were given clearance to be marketed as complementary medicines.

Comparison Of Complementary Medicines Processed In 2012 and 2013

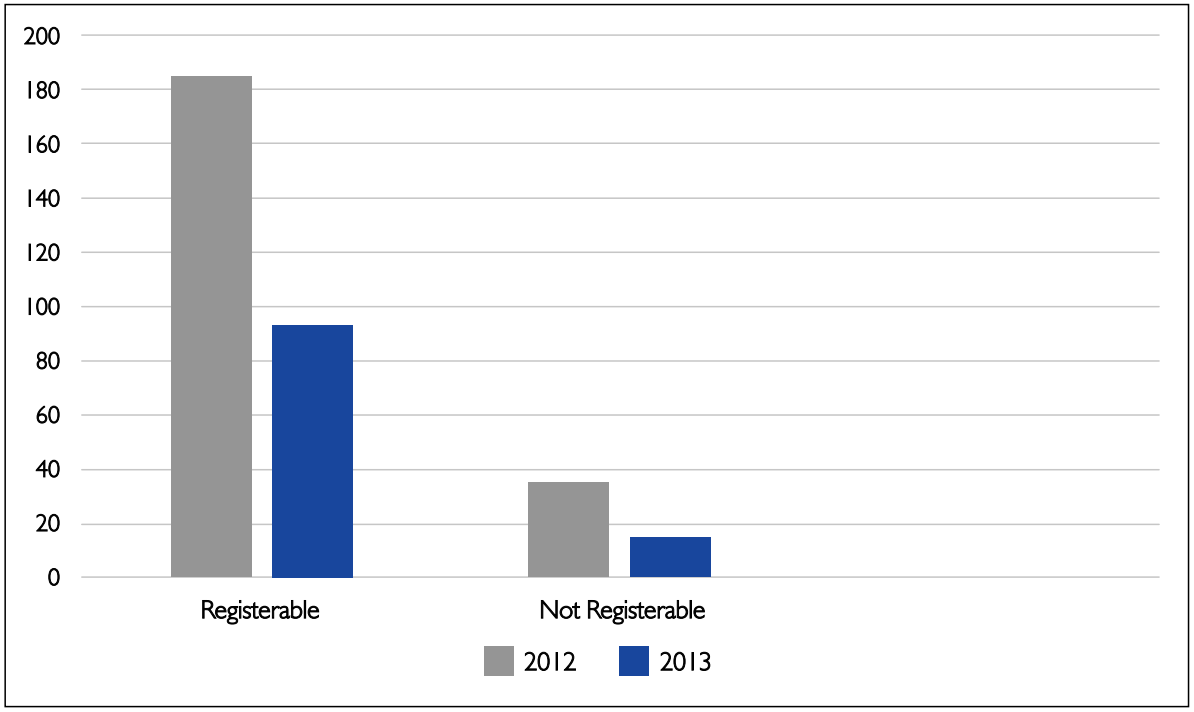


Figure 4: Number Of Complementary Medicines Received At MCAZ (*Source:* MCAZ Evaluations and Registrations December, 2013)

Meetings with Customers

MCAZ holds meetings with applicants to clarify application content requirements and procedural issues (Pre-submission Advice, Technical Advice and Clarification) in the interest of efficiency and transparency of the authorisation procedures. The Evaluations and Registration Division and Management jointly review the outcome of the meetings and any lessons learnt are applied to enhance continuous improvement and customer focus. One of the spin-offs of the system was identification of areas that will benefit from having new or clearer guidelines or information from frequently asked questions (FAQs).

Activities

- In 2013, a total of eighty eight (88) company meetings were held with applicants.

Registration Committee

A panel of external experts with medical, pharmaceutical and chemical expertise, derived from private practice, Ministry of Health and Child Care, City Health Authority, National Procurement Agency and Tertiary Health-Related Academic Institutions, nominated by their respective Professional Bodies and appointed by the MCAZ Board in liaison with the Minister of Health and Child Care, supports the MCAZ. The technical Committee sits once every month and considers assessment reports and recommendations made by the Secretariat. The Committee is mandated to make final decisions for approval or refusal of marketing authorization, on behalf of the Authority (MCAZ Board) which sits once every quarter. The Chairman of the Registration Committee, is a member of, and reports to, the Authority every quarter regarding the accomplishments and any challenges faced by the Registration Committee in the previous quarter. The

decisions of the Committees are ratified by the Authority. Landmark decisions made by the Registration Committee are discussed to inform policy in the ever-changing regulatory landscape.

Veterinary Committee

A panel of external experts with veterinary, pharmaceutical and chemical expertise, derived from private veterinary practice, Ministry of Agriculture Division of Veterinary Services, and Tertiary Health-Related Academic Institutions, nominated by their respective Professional Bodies and appointed by the MCAZ Board in liaison with the Minister of Health and Child Care, supports the MCAZ. The Committee sits once every two months and considers assessment reports and recommendations made by the Secretariat. The Committee is mandated to make final decisions for approval or refusal of marketing authorization, on behalf of the Authority (MCAZ Board) which sits once every quarter. The Chairman of the Veterinary Committee, is a member of, and reports to, the Authority every quarter regarding the accomplishments and any challenges faced by the Veterinary Committee in the previous quarter. The decisions of the Committees are ratified by the Authority. Landmark decisions made by the Veterinary Committee are discussed by the Board to inform policy.

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.

Activities

- At the end of 2013, a total of nine hundred and eight (908) licences and permits had been issued to companies that manufacture, distribute and dispense medicines. One hundred and thirty-two of these were new licences and permits whilst the rest were renewals. This represented an increase of seventeen point five percent (17.5%) from the previous year.
- One-hundred and thirty-two (132) new premises licences and permits were issued in 2013, seventy-seven (77) of which were pharmacy licences, twelve (12) wholesale dealer's permits, fifteen (15) industrial clinics licences, eighteen (18) veterinary medicines general dealers' permits and seven medical and practitioners' practices licences.

Comparison of new premises licences and permits issued in 2012 and 2013

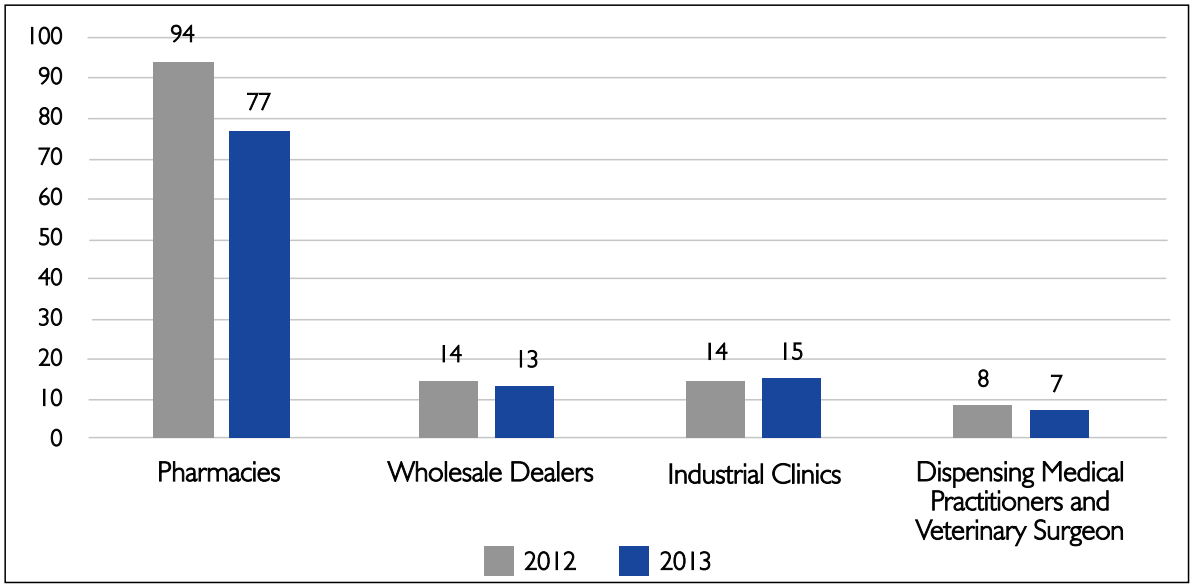


Figure 5: New Premises Licences And Permits Issued By MCAZ

Comparison of the total number of licences and permits issued in 2012 and 2013

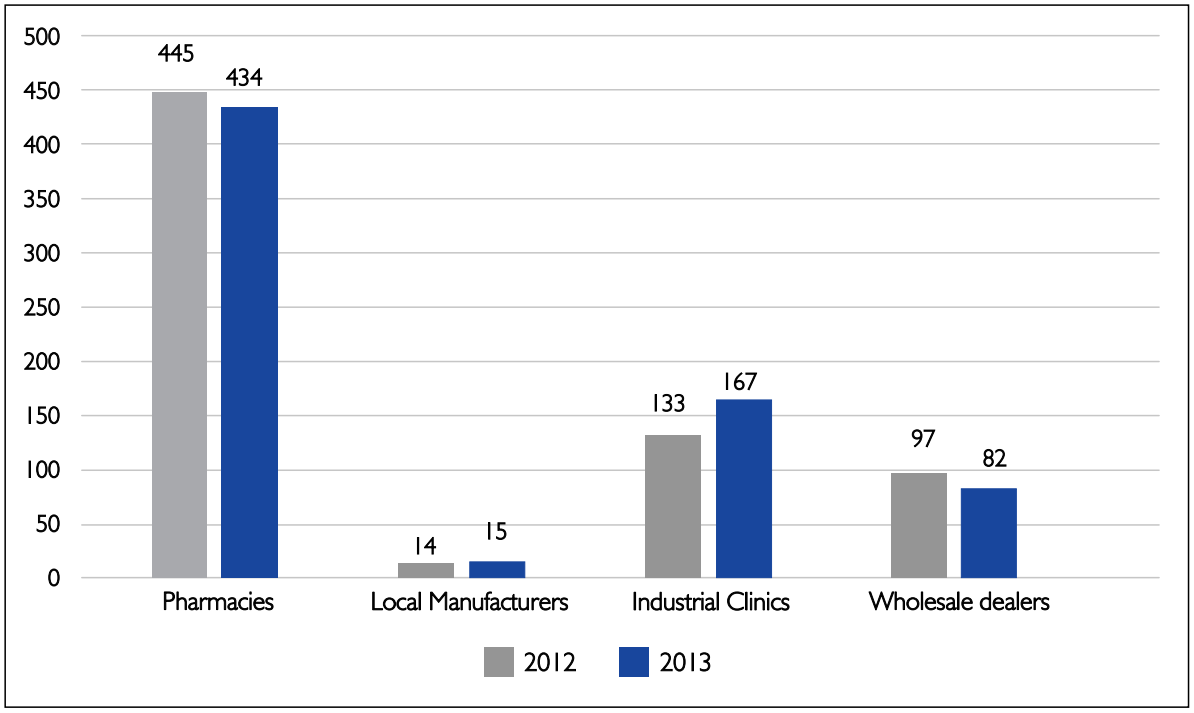


Figure 6: Premises Licences And Permits Issued By MCAZ.

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, upon submission of satisfactory applications.

Activities

- In 2013, one thousand one hundred and forty-five (1145) professionals were licensed to dispense, and/or deal in medicines. This represents a decrease of fourteen percent (14%) from the previous year.

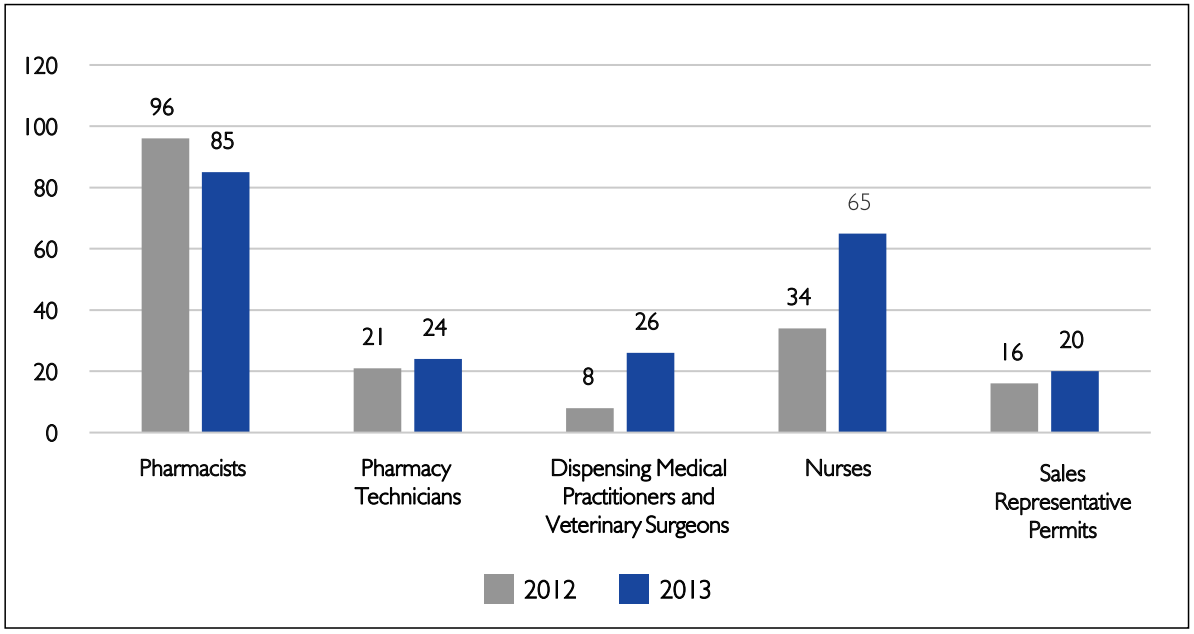


Figure 7: New Persons Licences Issued By MCAZ

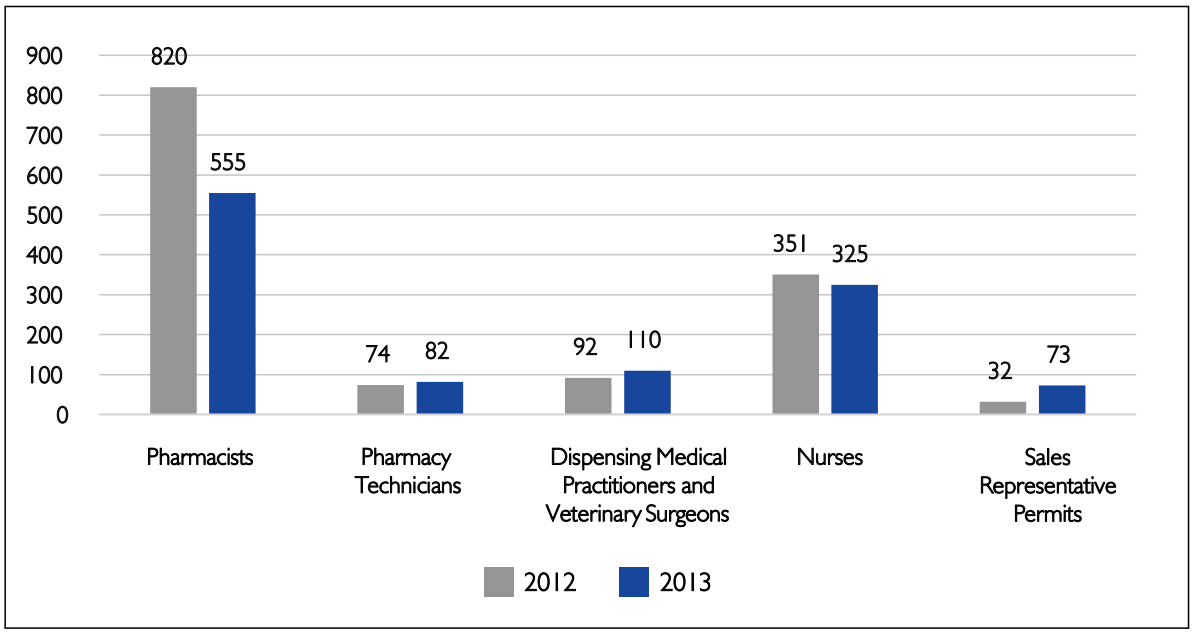


Figure 8: Total Number Of Person Licences And Permits Issued

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 and authorises quantities for up to six (6) months at a time.

Activities

- The number of section 75 applications processed in 2013 for human use came to a total of six thousand seven hundred and seventy-nine (6779), which was an increase of fifty-three percent (53%) compared with those processed in 2012. The most commonly applied for products were Alendronic acid tablets, Amphotericin B vials, Baclofen, Bisoprolol, Bupropion, Carvedilol, Citalopram, Rosuvastatin, Finasteride, Pregabalin, Levodopa-Carbidopa, Gabapentin, Perindopril, Oxybutinin, Sertraline, Tramadol, Venlafaxine, Vitamin B Complex injection and Vitamin B12 Injection. This then resulted in the introduction of the Bulk Importations by Wholesaler for these products to enable quicker access to these medicines and also to ultimately encourage registration of the products.
- Four hundred and fifty three (453) of the section 75 authorisations issued for human medicinal products came from institutions and six thousand three hundred and twenty-six (6326) were for individual prescriptions.
- Seventy-three (73) Section 75 authorisations were issued for veterinary medicines.

Comparison of authorisations issued in 2012 and 2013

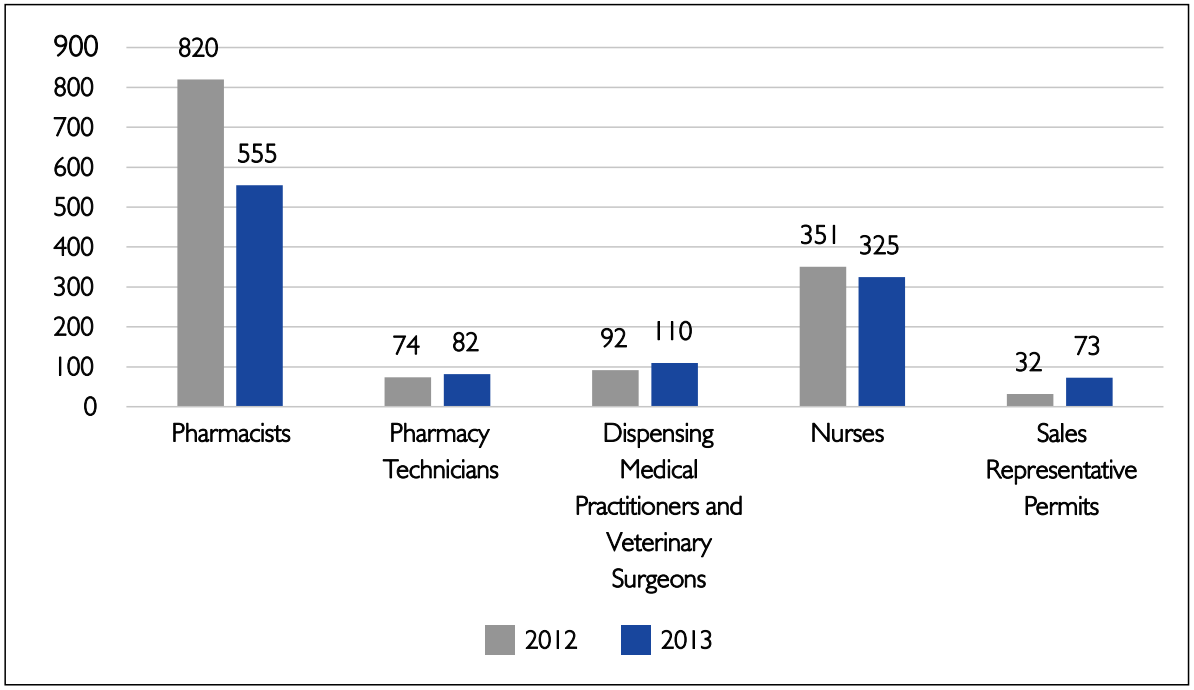


Figure 9: Number Of Section 75 Authorisations In 2013

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.

Activities

- 198 donations were approved for entry into Zimbabwe in the year 2013.

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). It is also responsible for 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 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.

Activities

- In 2013, one hundred and seven (107) licences to import narcotics and psychotropic substances were issued. Fifty (52) licenses to possess, acquire and administer narcotics were issued, including game capture licences
- One hundred and twenty three (123) permits for the importation of precursor substances were issued.

Comparison of licences and permits issued in 2012 and 2013

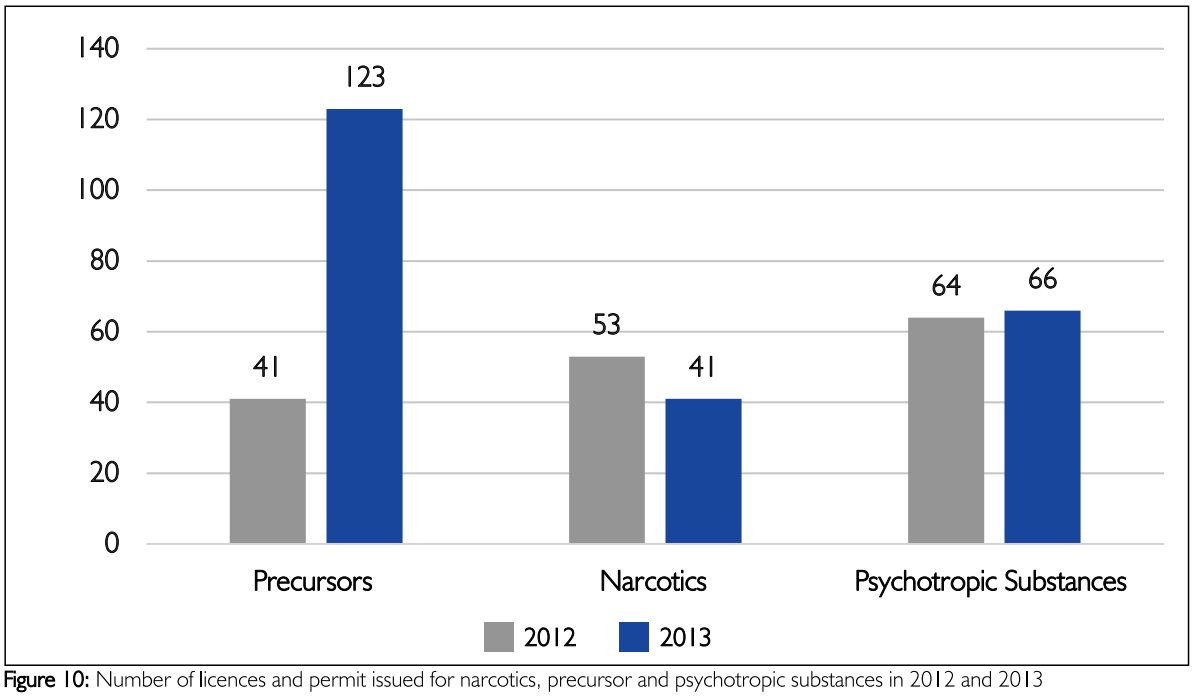


Figure 10: Number of licences and permit issued for narcotics, precursor and psychotropic substances in 2012 and 2013

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 and/or Good Distribution Practices (GDP) for wholesalers. Pharmacies, dispensing medical practices or veterinary practices, and health institutions are also inspected for good dispensing practices in line with the requirements of the legislation. MCAZ aims to inspect all licenced premises at least once every two years.

Activities

- A total of three hundred and twenty-six (326) inspections of licensed premises were carried out by the MCAZ Inspectorate in 2013 compared to three hundred and seventy-six (376) in 2012.
- In 2013, an additional eighty-five (85) inspections of approved public institutions, mainly mission hospitals, were carried out with support from the Health Transition Fund and UNDP compared to the seventy-three (73) conducted using support from the Health Transition Fund in 2012.
- MCAZ carried out thirty (30) special investigational inspections in 2013 compared to ninety-three (93) in 2012.

Comparison of inspections in 2012 and 2013

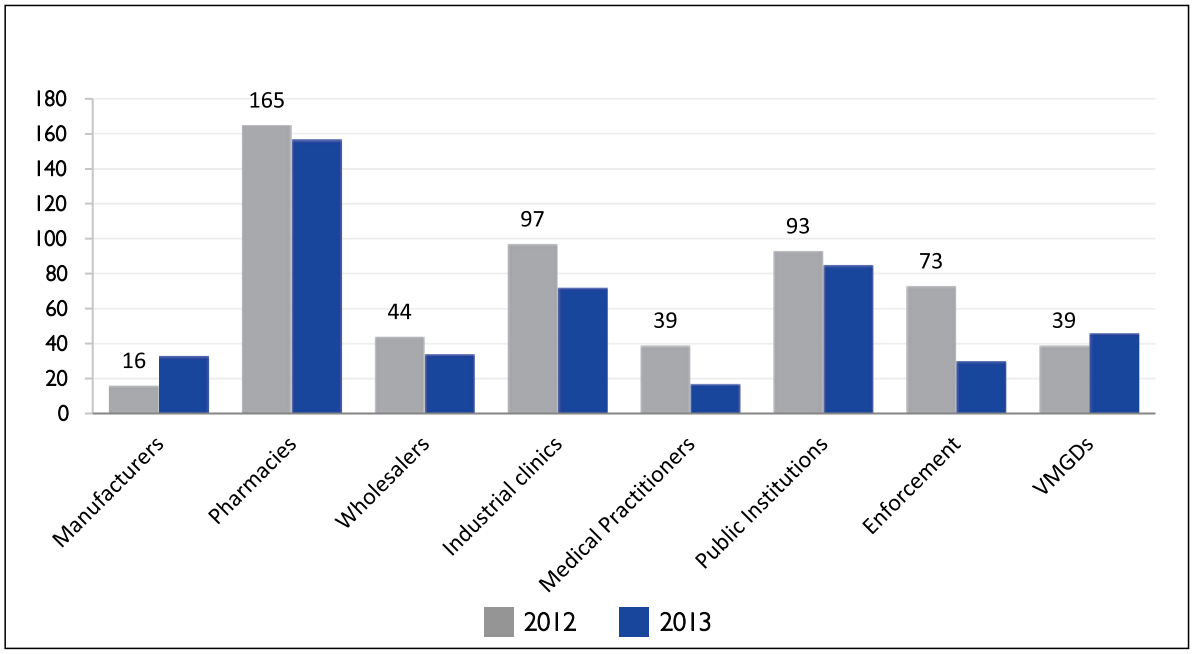


Figure 11: Comparison of Inspections in 2012 and 2013.

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 registered medicinal products through designated ports.

Activities

In 2012, one thousand and nineteen (1019) import permits were issued as compared to one thousand one hundred and forty-seven (1147) in 2013. There was an increase in the number of export permits issued in 2013 as 86 permits were processed as compared to 54 in 2012.

Comparison of permits processed in 2012 and 2013

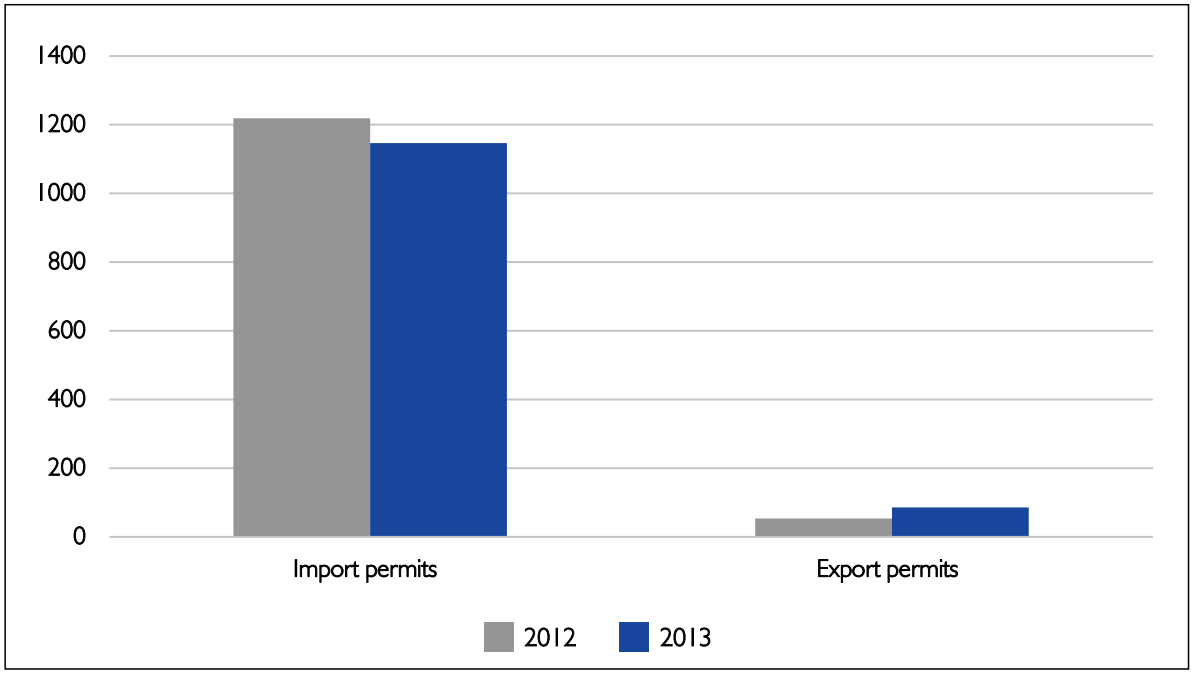


Figure 12: Comparison of Permits Processed in 2012 and 2013

- A single port of entry, namely Beitbridge Border Post had two MCAZ monitoring visits during the course of the year. The monitoring visits were conducted in order to assess the movement of medicines through the ports of entry and to provide support to the port officials. Training was also imparted to the port officials during one of the monitoring exercises. The decrease from seven (7) from the previous year was due to the cessation of funding from the Health Transition Fund.
- Harare International Airport continued to be monitored daily from Monday to Friday each week and all consignments containing medicines were physically verified.
- MCAZ continued to work in collaboration with ZIMRA and Port Health Officials. To that effect, over sixty (60) ZIMRA & Port Health officers were trained to assist with clearance of medicines at ports not physically monitored by MCAZ at present.

- In order to assist the prosecutors and police in the understanding of laws relating to medicines a total of eleven public prosecutors from Harare, Chitungwiza and Mbare Courts, four officers from the Attorney General's office in Harare and thirteen detectives with the CID drugs Harare and Bulawayo offices were trained on the laws relating to medicines.

Licensing and Advertising Committee

This is a committee of the Authority comprising of a panel of experts which assesses and approves or refuses to approve applications for premises and person's licences or permits. The Committee is also responsible for providing general policy guidance on licensing and advertising matters, and making recommendations to the Authority where so required.

Activities

During the course of 2013 the Licensing and Advertising Committee held eleven (11) scheduled meetings. At these meetings the Licensing and Enforcement Division reported on matters to do with inspections, enforcement as well as advertising issues. The panel of experts considered inspection reports and representations from applicants and licensees in the licensing of premises and persons.

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, product recalls and annual retentions of registered medicines.

PHARMACOVIGILANCE

Reports on adverse reactions are evaluated and recorded in the international drug-monitoring database (WHO UMC VigiFlow). The reporting professionals receive appropriate feedback. In addition, reports of adverse reactions from within Zimbabwe reach MCAZ through the pharmaceutical companies. We acknowledge with thanks the funding received from HTF, 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.

Activities

Pharmacovigilance

In 2013 the Authority received a total of 728 (representing 100% of the safety reports), that included 52 (7%) Adverse Drug Reaction (ADR) spontaneous reports, 320 (44%) ADR reports from Targeted Spontaneous Reporting of ARVs, anti-tuberculosis and all essential medicines, 39 (5%) from Adverse Events Following Immunizations (AEFI) reports, 72 (10%) Serious Adverse Events (SAE) reports from pharmaceutical industry, and 245 (34%) SAE reports from authorised clinical trials of medicines and vaccines conducted in Zimbabwe, see Figure 13 below. All reports (ADRs, AEFIs, & SAEs) were processed and causality assessment was done monthly by the MCAZ Pharmacovigilance and Clinical Trials (PVCT) Committee and written feedback provided to the reporters. The reports 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.

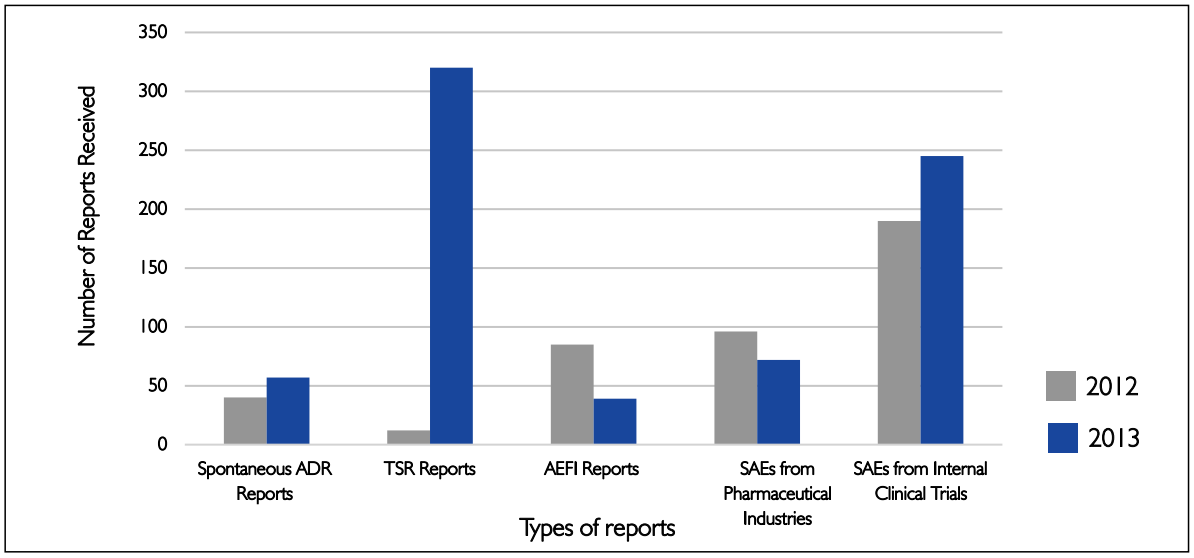


Figure 13: Cumulative Summary PVCT Division activities from January 2012 to December 2013

(Source: MCAZ, Pharmacovigilance and clinical trials; 2012-2013

The pilot phase Targeted Spontaneous Reporting (TSR) of Anti-retrovirals (ARVs), Anti-TBs and essential medicines program was conducted from October 2012 to September 2013 in 8 provinces (Manicaland, Mashonaland East, Harare & Chitungwiza, Masvingo, Midlands, Bulawayo, Matabeleland North and Matabeleland). A total of 300 healthcare professionals that included 47 (16%) medical doctors, 92 (31%) nurses and 103 (34%) pharmacy staff, 58 (19%) others were trained. Please see Figure 13 and 14. The impact of the TSR of ARVs, Anti-TBs and essential medicines resulted in a six (6) fold increase of ADR reporting and most sites that were previously not submitting ADR reports are now submitting such reports, see Figure 14 below. The progress report of the pilot phase of the TSR of ARVs and Ant-TBs was published in the MCAZ Drug Information Bulletin June 2013 issue. A full article will be published in a reputable drug safety journal in the near future.

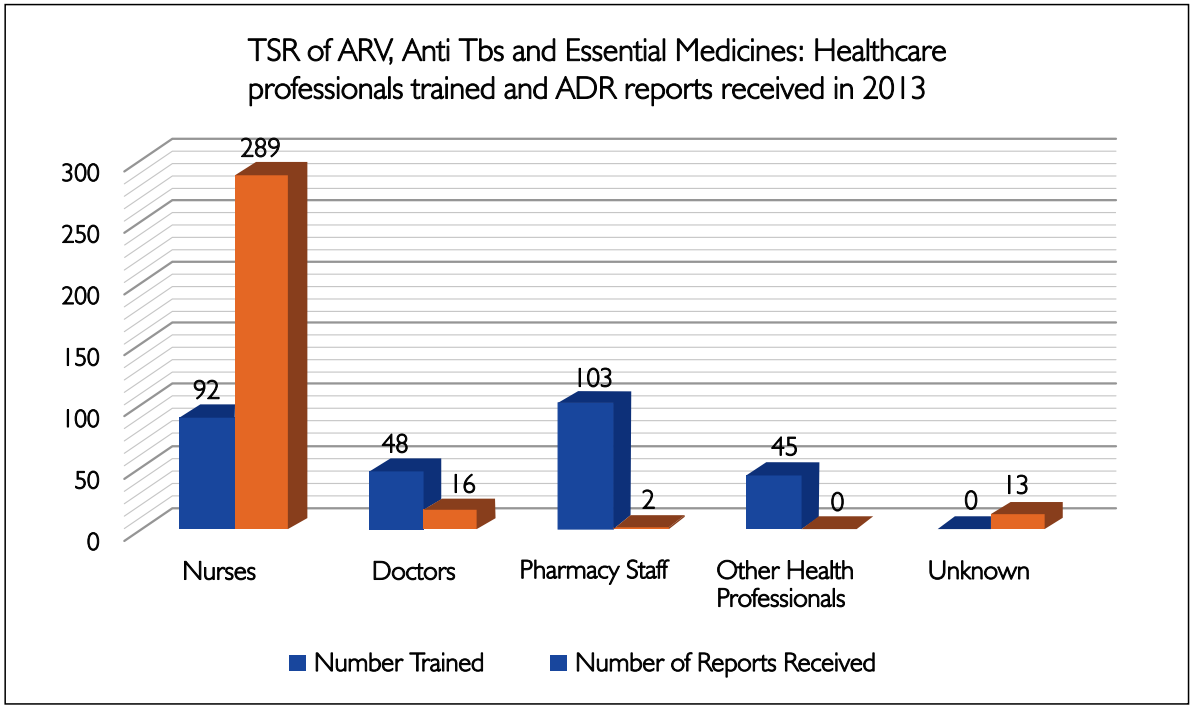


Figure 14: TSR of ARVs, Ant-TBs and Essential Medicines Program, Number of Healthcare Professionals Trained and ADR Reports Received In 2013

The scale up Targeted Spontaneous Reporting (TSR) main phase

This is being conducted from October 2013 until the end of 2015. Further trainings and follow ups will involve all the ten provinces including Mashonaland Central and Mashonaland West. Staff at the MCAZ, the national pharmacovigilance centre, in collaboration with the MoHCC, National AIDs and TB programme hospitals and clinics 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 the program implementation, monitoring and evaluation.

Post marketing surveillance activities identified some product defects, and recall of 2 products were carried out. One

batch of Oxytocin 5IU/ml injection batch number HZ001 manufactured by Umedica Pharmaceuticals was recalled due to lack of effectiveness in one district hospital. Sodium Bicarbonate 8.4% w/v 100ml injection, batch numbers 121838022 and 123518022, were recalled due to precipitation. This was caused by a change in the primary closure to a bromobutyl stopper. The manufacturer, B Braun, rectified the problem by switching back to EPDM (ethylene-propylene rubber) stoppers.

Zimbabwe National Pharmacovigilance guidelines:

Following consultative meetings held in 2013, PVCT Division published the Zimbabwe National Pharmacovigilance Policy and Guidelines Handbook 1st Edition November 2013 and National Guidelines for Adverse Events Following Immunisation (AEFI) guidelines and revised the AEFI Reporting Form to be in line with the Brighton Collaboration guidelines.

Strengthening National Surveillance of Adverse Events Following Immunisation

The MCAZ acknowledges with thanks the AEFI reports received from ZEPI and the joint MCAZ & ZEPI AEFI surveillance including training of EPI staff countrywide over the years. Comprehensive analysis of the spontaneous AEFI reports following immunization was done using HTF funding during the January to March 2013 period following concern over a slight increase in fatal AEFIs in 2012, totalling seven (7), compared to zero or one (1) or two (2) deaths per year in previous years. There was however a decrease in the number of death AEFI reported cases in 2013 to one, see Figures 15 and 16. The AEFI reports were put through a causality assessment process by the MCAZ Pharmacovigilance and Clinical Trials (PVCT) Committee. AEFI data entry was uploaded onto the WHO Vigiflow database. The slight increase of suspected fatality AEFIs could be due to the increased rate of AEFI reporting as a result of the MCAZ & ZEPI AEFI trainings country wide from 2011 to 2013. The Pharmacovigilance and Clinical Trials Committee, at its 111th meeting held on 8th May 2013;

a) Noted that the whole system of the National Immunization programme for Zimbabwe (ZEPI) and AEFI surveillance required basic capacity building such as emergency medicines kits for the management of AEFIs at all vaccination clinics countrywide. The MoHCC was therefore encouraged to procure basic emergency medicines kits for the management of AEFIs.

b) Affirmed the need for the MoHCC to strengthen AEFI surveillance by ZEPI and MCAZ considering that new vaccines such as Rotavirus and HPV will soon be introduced.

As a result, four joint MCAZ and EPI-MoHCC AEFI surveillance trainer of trainers (TOTs) trainings were conducted countrywide in 2013 at the EPI review meetings

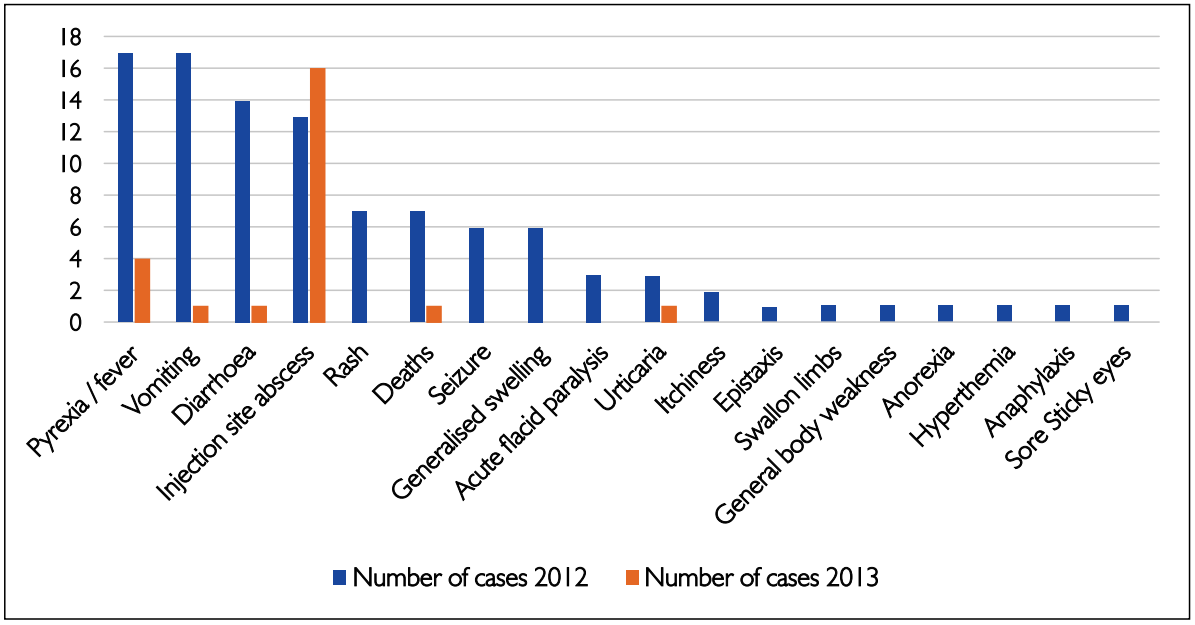


Figure 15: Spontaneous AEFI Reports Following 2012 And 2013 EPI National Immunisation Days

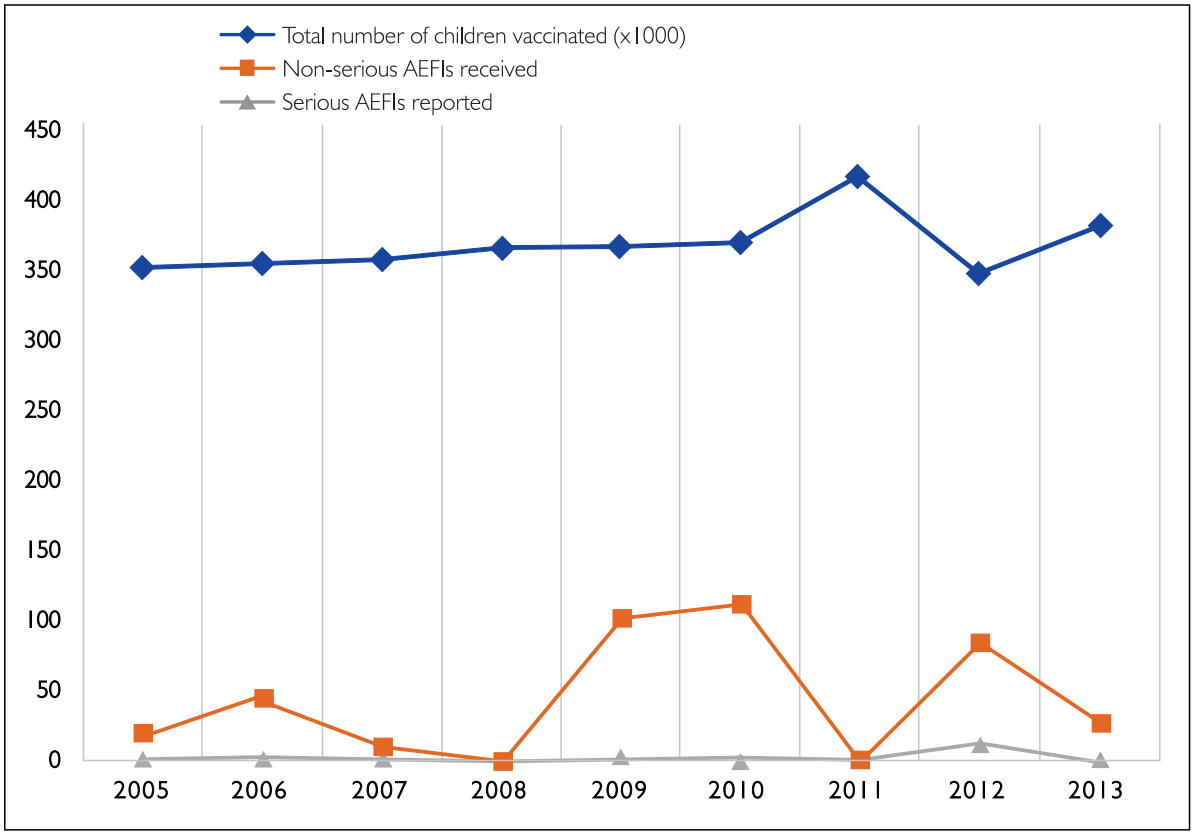


Figure 16: Comparison of EPI Denominator data for vaccinated Children vs Spontaneous AEFIs and serious AEFI reports received by MCAZ

POST-REGISTRATION AMENDMENTS AND APPLICATIONS FOR RE-INSTATEMENTS

Applications must be made for approval of any variations/amendments to medicinal products registered by MCAZ. A final list of minor variations can be submitted as variations that are subject to notification. Any other variations to a medicinal product are subject to approval. These applications are evaluated and approved by the Registration Committee.

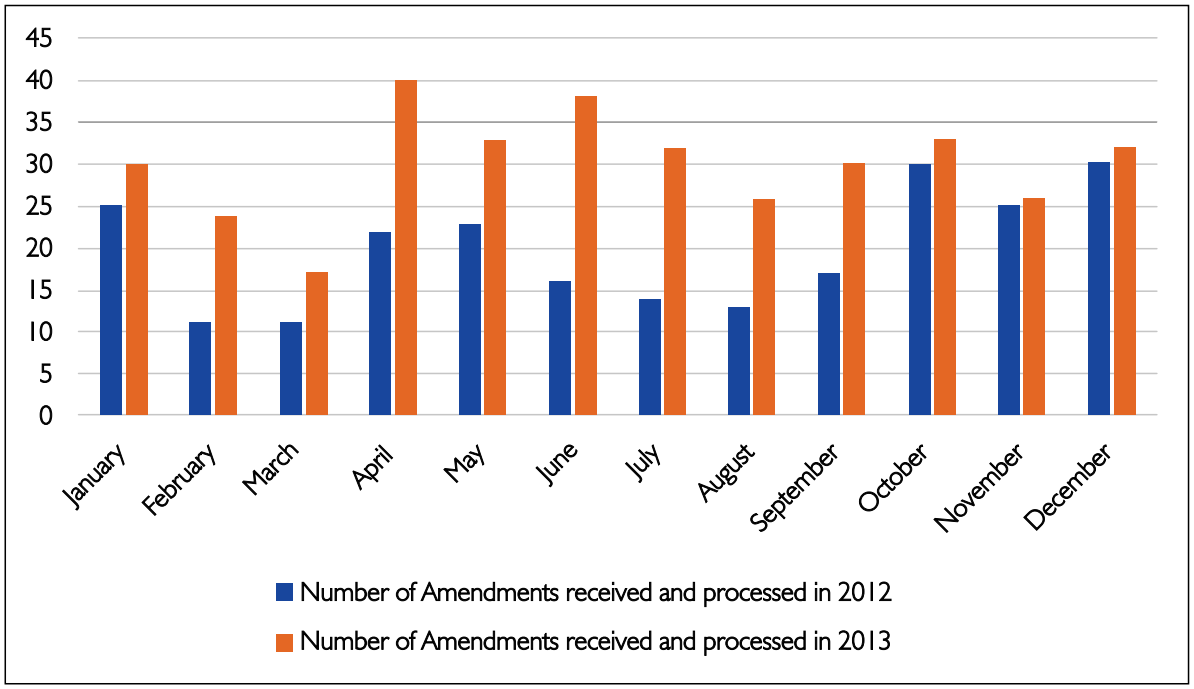


Figure 17: Number of Amendments received and processed in 2012 and 2013

Activities

- In 2013, 361 applications for approval of variations/amendments to registered medicines were submitted and processed, see Figure 17 above.
- A few amendments received in 2012 were still ongoing owing to the submission of inadequate information by applicants.
- A total of twenty-five (25) applications for re-instatement of registration of cancelled products were received and processed.

ANNUAL RETENTION OF REGISTERED MEDICINES:

Comparison of registered medicines maintained on the MCAZ register due to payment of annual retention for human and veterinary medicines:

In order to maintain a human and veterinary medicinal product on the register of approved medicines, payment of an annual retention fee is required. The applicant must apply for the medicinal product to be retained. The registration status of the product is retained for the next year if the conditions continue to be met. Notification is required if a medicinal product is no longer distributed: notification must be given at least two months before distribution ceases.

Activities

- In 2013, 98% of the foreign human medicinal products, 95% of the local human medicinal products, 90% of the foreign veterinary medicinal products and 96% of the local veterinary medicinal products were retained on the market. Other products (2.5%) had their registrations cancelled due to non-payment of the 2013 retention fees by the applicants. Please see Figure 18 below;

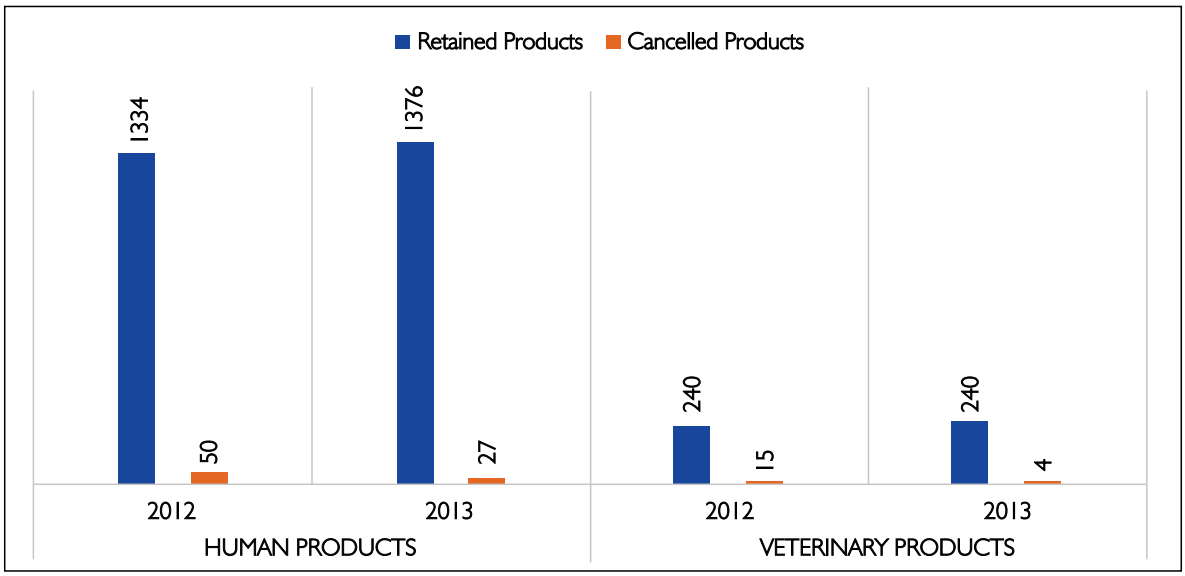


Figure 18: A Comparison of Retained Registered Products versus Cancelled Products from 2011 to 2013.

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

Activities

- In 2013, thirteen clinical trial applications were received and authorised. Monitoring of compliance with GCP was done by conducting 8 GCP inspections and processing of SAEs, amendments to clinical trials, and review of data safety monitoring board (DSMB) reports. Several applications for importation of clinical trial investigational medicines were received in 2013 and processed as per the approved protocols.
- A total 245 (34% of total Individual Case Safety Reports) SAE reports were received from 36 authorised clinical trials of medicines and vaccines conducted in Zimbabwe, see Figure 13. Most SAEs were as per the product safety labelling and patients were managed appropriately.

CHEMISTRY LABORATORY

The ISO/IEC 17025 accredited laboratory holds the responsibility for the chemical analysis of medicinal products and allied substances. Quality control testing (chemical) of ARVs, anti-malarial, anti-TB drugs and other conventional medicines is carried out in the Chemistry laboratory. Samples are analyzed for the purposes of;

a) Registration
b) Post-market surveillance
c) Pre-distribution analysis for Ministry of Health and Child Care (MOHCC) and Non-Governmental Organizations (NGO's) like UNICEF and UNDP.
d) Adverse event monitoring.

KEEPING ABREAST WITH GLOBAL STANDARDS

ISO/IEC 17025 ACCREDITATION

The Chemistry Laboratory was audited on the 6th of November 2013 by the SANAS auditors. The ISO/IEC 17025:2005 accreditation was retained for the following techniques: High Performance Liquid Chromatography (HPLC) and Ultraviolet-Visible (UV- Vis) technique. The technical signatories for the two techniques added up to four.

WHO PREQUALIFICATION

During the course of the year the laboratory worked assiduously towards WHO Prequalification, refining the quality management system to suit the WHO Prequalification requirements thereby enhancing the robustness of the quality control system of the national pharmaceutical quality control facility

Activities

Proficiency Testing (PT) Participation

A PT scheme is an inter-laboratory system of regular testing of the accuracy that the participating laboratory can achieve. The Chemistry Laboratory participated in five inter-laboratory PT schemes and performed satisfactorily.

Quality Control Activities

At the end of 2013, 346 sample products had been received for analysis. 246 were analyzed and 11 failed analysis. A reflection of the productivity of the laboratory in 2013 is depicted in Figure 19 below.

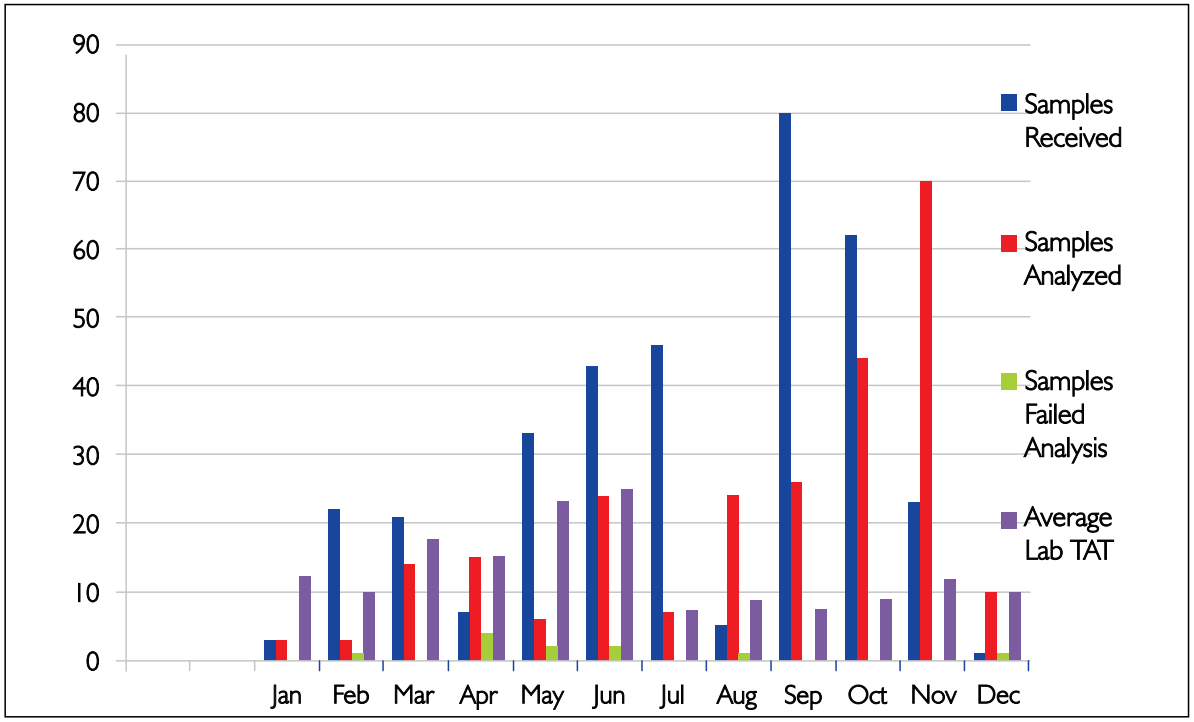


Figure 19: Summary Of Sample Products In The Chemistry Laboratory In 2013 (Source: MCAZ Chemistry Laboratory, 2014)

SAMPLES ANALYSIS SUMMARY FOR YEAR 2013

Month	No of Samples Received	No. of Samples Analyzed	No of Samples Failed Analysis
January	3	3	0
February	22	3	1
March	21	14	0
April	7	15	4
May	33	6	2
June	43	24	2
July	46	7	0
August	5	24	1
September	80	26	0
October	62	44	0
November	23	70	0
December	1	10	1
TOTAL	**346**	**246**	11

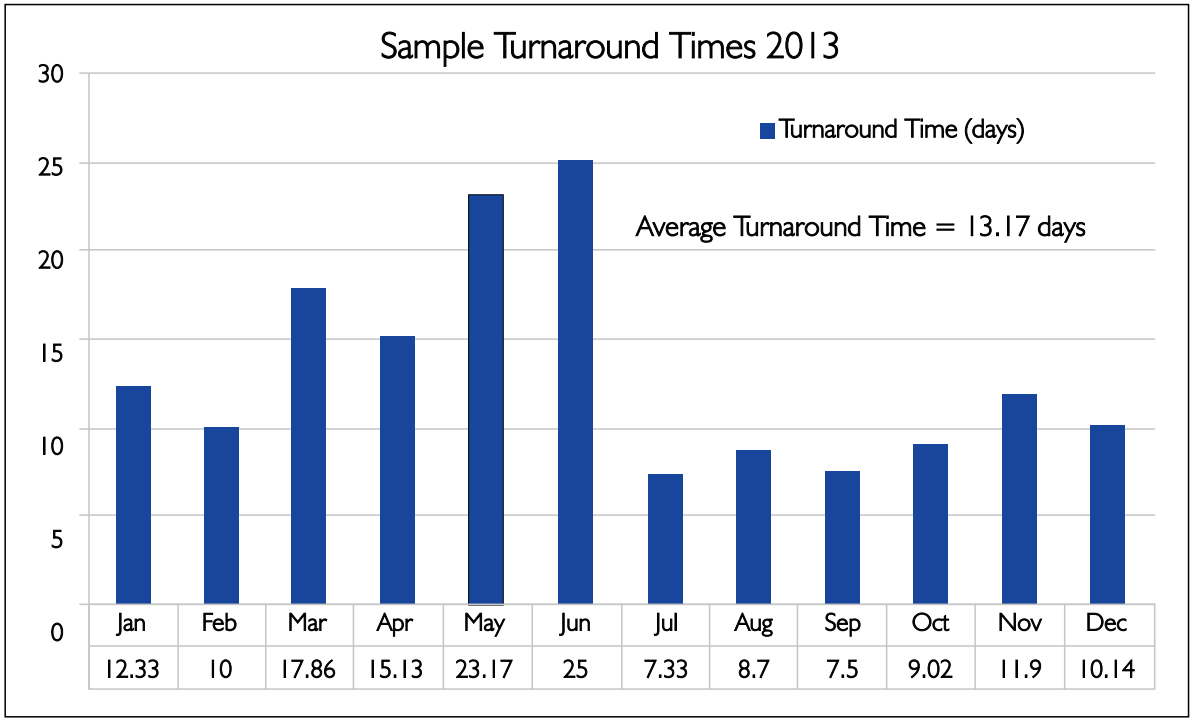


Figure 20: Sample Turnaround Times

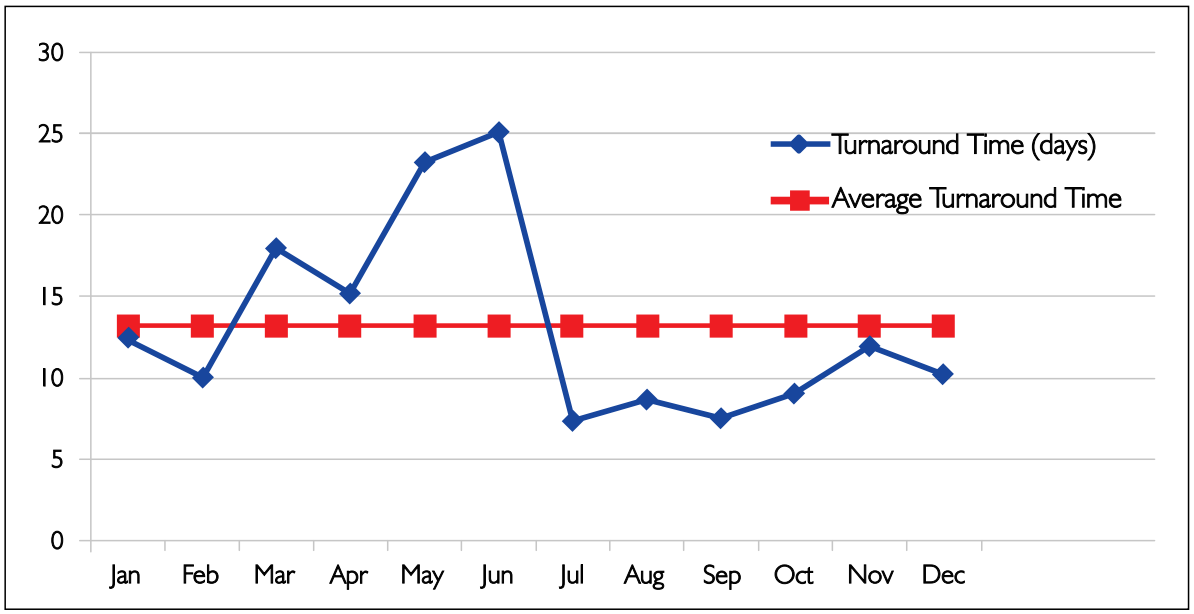


Figure 21: Average Turnaround Time

STATISTICS ANTI-RETROVIRALS, ANTI-TUBERCULOSIS AND ANTI-MALARIALS AND OTHER FOR YEAR 2013

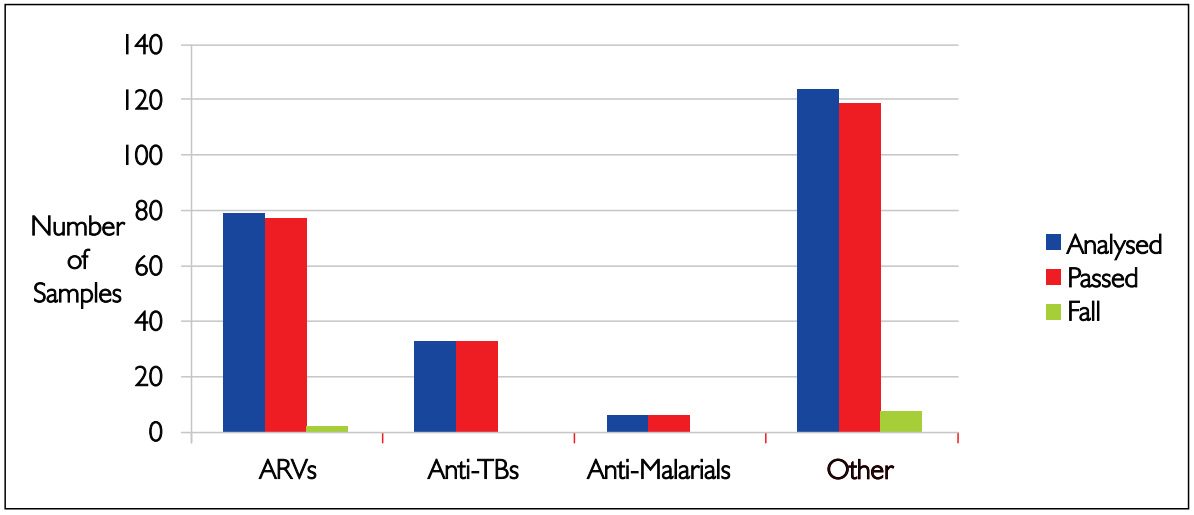


Figure 22: Statistics: Anti-Retrovirals, Anti-Tuberculosis and Anti-Malarials and Other

DRUG TYPE	ANALYSED	PASS	FAIL
ARVs	80	78	2
Anti-TBs	33	32	1
Anti-Malarials	9	9	0
Other	124	116	8
TOTAL	246	235	11

Laboratory Committee

A panel of experts supports MCAZ in the assessment and provision of advice relating for the laboratory testing for product registration, post-marketing surveillance, routine product samples and human and veterinary medicinal products and medical devices.

Laboratory Capacitation in the scope of activities

UNDP Global Fund Round 8 Support

The Chemistry Division received funds totalling US$143 000 as support from the Global Fund Round 8 mainly for the laboratory renovations to ensure a GLP and cGMP compliant environment for the laboratory staff.

HTF / UNICEF Support:

Testing fees for post market surveillance for essential medicines were received from the Health Transition Fund (HTF). Samples were collected from the ten provinces around the country. This was a way of monitoring the robustness of the distribution chain.

MCAZ Post Market Surveillance (PMS) as a Regulatory Function

- One of the activities of the Chemistry laboratory is to conduct quality control activities on post-registration samples for quality, safety and efficacy. This activity has come to fruition due to funding from two donor partners UNICEF and UNDP/Global Fund. The PMS activities have always been an essential means of monitoring manufacturers/distributors for good manufacturing and good laboratory practices as well as good distribution practices.
- Being able to assess performance of manufacturers on cGMP through testing is a plus as this enables the Authority to quickly permit medicines release into the public sector depending on the source/manufacturer of the product.

MEDICAL DEVICES AND MICROBIOLOGY UNIT

Microbiology Laboratory

The Microbiology Laboratory, guided by the Medicines and Allied Substances Control Act, examines products for pathogenic and non-pathogenic microorganisms, assesses potency, and reviews microbiological data, and evaluates biopharmaceuticals including vaccine lot release.

Activities

- There was a 118% increase in the number of samples received in 2013 as 212 samples were received compared to 97 received in 2012.
- Complementary Medicines dropped from 16% in 2012 to less than 10% in 2013 of the total number of samples. This may be as a result of greater proficiency in terms of the process of authorisation to distribute these medicines being effected by the Evaluations and Registration Division.
- The increase in allopathic medicines as shown in Figure 23 may be as a result of an increase in the number of samples submitted for Post Market Surveillance projects funded by UNICEF and UNDP.

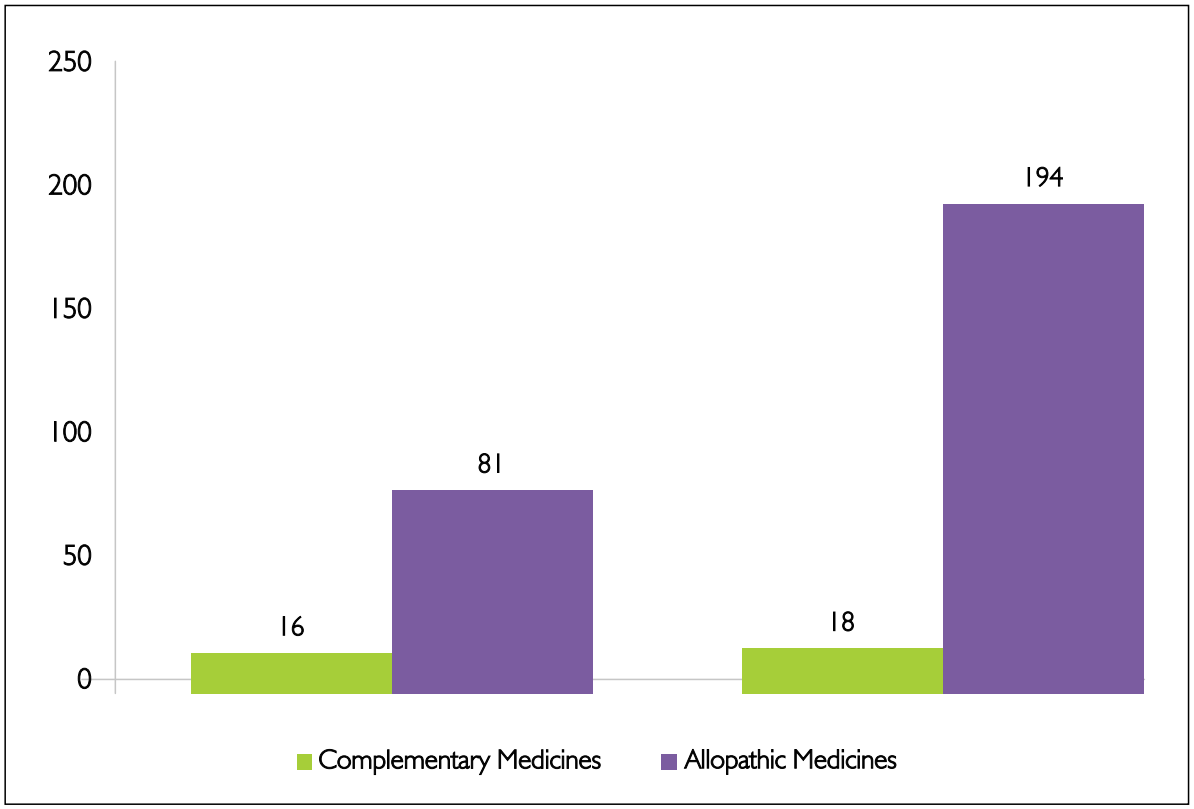


Figure 23: Types of Medicines Received in the Microbiology Laboratory

MEDICAL DEVICES AND MICROBIOLOGY UNIT

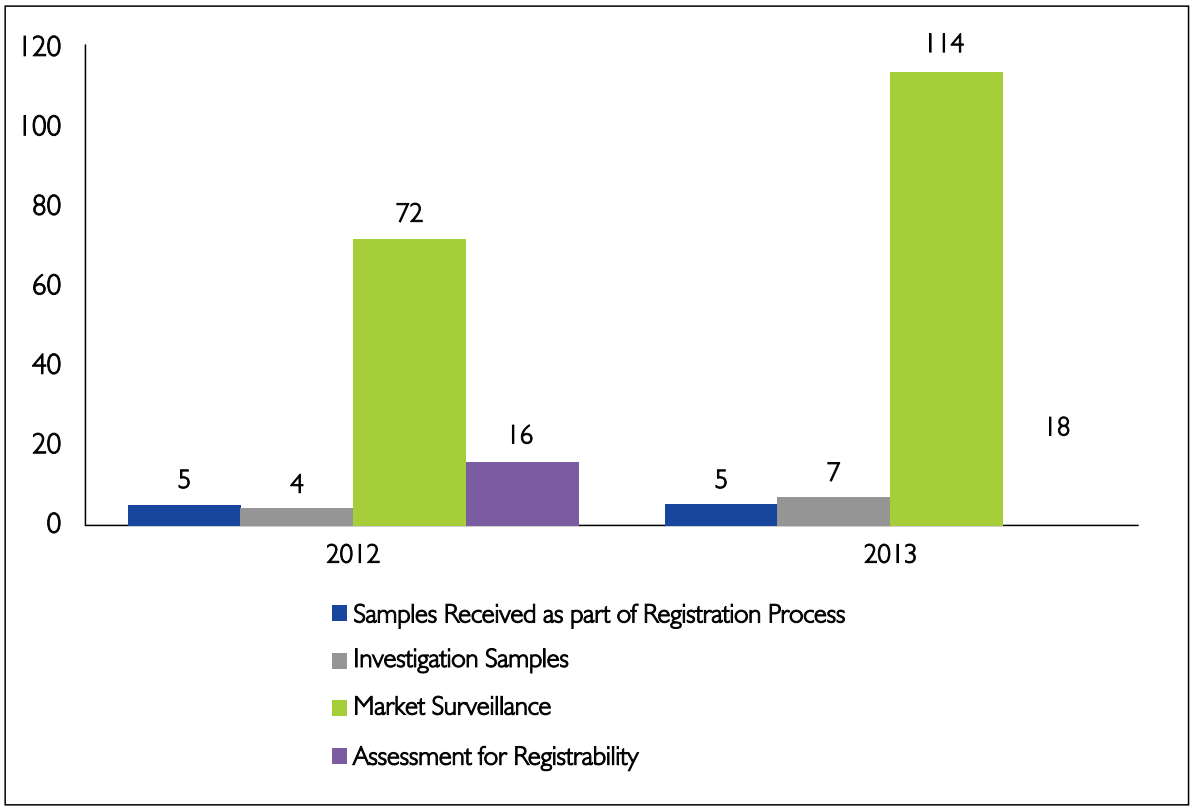


Figure 24: Types Of Samples For Analysis Received In The Microbiology Laboratory

Vaccine Lot Release

- Vaccines, as biological, require assessment per batch manufactured before approval for use. Hence every batch of vaccine imported has to be assessed for quality.
- The Vaccine Lot Release function is still in its infancy, the laboratory having only started the process at the end of 2011, hence compliance from stakeholders is yet to be consistent. There is also a skills gap which needs to be filled through training of people in the Unit.
- There was a decrease in the total number of vaccine summary lot protocols (VSLPs) submitted for release from 55 in 2012 to 33 in 2013, translating to a 41% decrease (Figure 25).
- Figure 26 shows submissions compared between the private sector and the Zimbabwe Expanded Programme for Immunisation in collaboration with EPI-UNICEF under the Ministry of Health and Child Care. ZEPI submitted the most VSLPs in 2012. However there was a drop of VSLPs submitted by ZEPI from 31 in 2012 to 13 in 2013. The drop from private sector was minimal from 25 in 2012 to 20 in 2013.

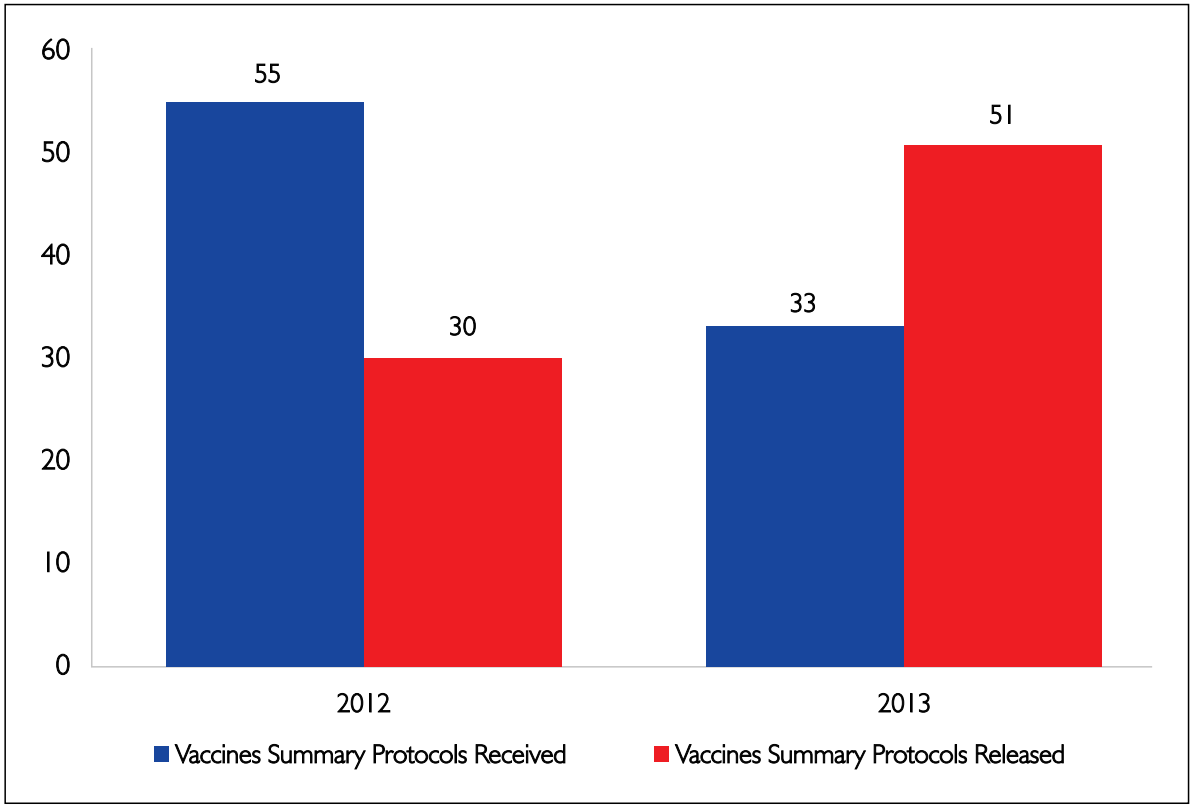


Figure 25: Vaccine Summary Lot Protocols Received In The Microbiology Laboratory

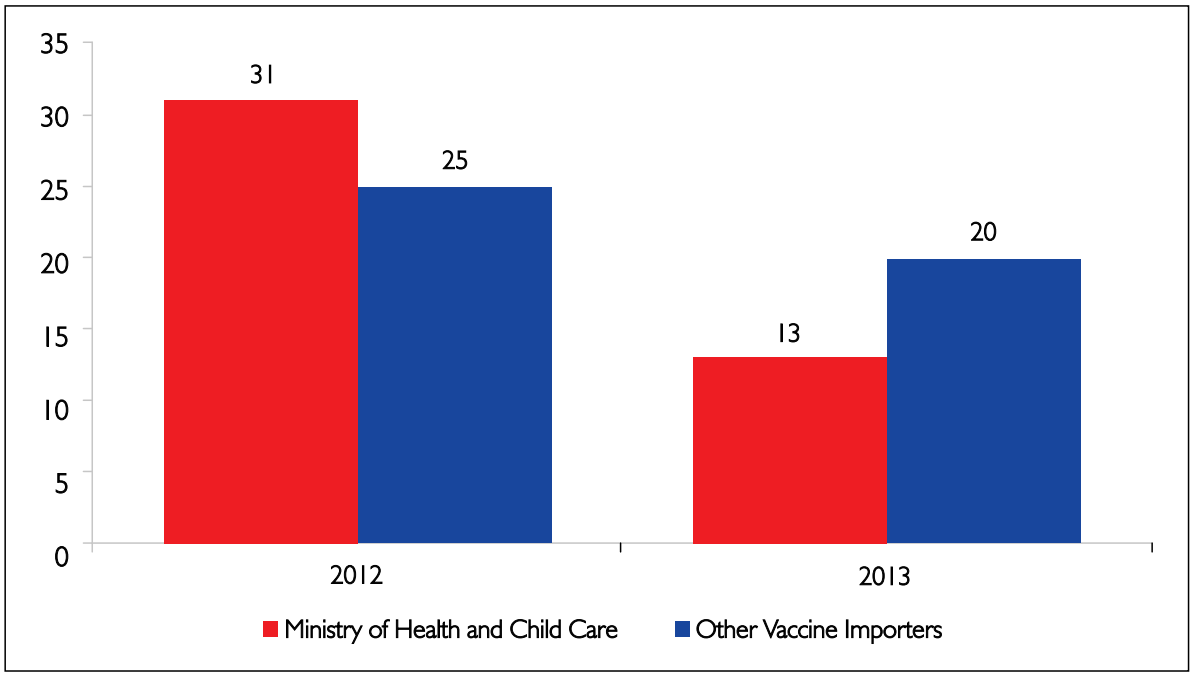


Figure 26: Comparison Of Vaccine Summary Lot Protocols Received Between MoHCC And Other Private Importers

Medical Devices Laboratory

The Medical Devices laboratory examines gloves and condoms under the purview of the Medicines and Allied Substances Control Act. The laboratory does conformity assessment of condoms and gloves as guided by the ISO requirements and MCAZ regulations. The laboratory is ISO/IEC 17025 accredited by SANAS for condom testing.

Activities

- There were 451 condom samples received in 2013, an increase of 16% compared to 387 samples received in 2012.
- The inflow of glove samples was not very consistent for the past 2 years. There appears to be a decrease in the number of samples submitted on an annual basis, however, in 2013 there were 110 samples received, compared to 44 received in 2012 translating to a 150% increase.
- The number of new registrations for both gloves and condoms continues to increase steadily.
- The laboratory participates in proficiency testing schemes coordinated by the Family Health International (FHI360), USA and Enersol of Australia.

Figure 27: Condom Samples Received For Analysis In The Medical Devices Laboratory

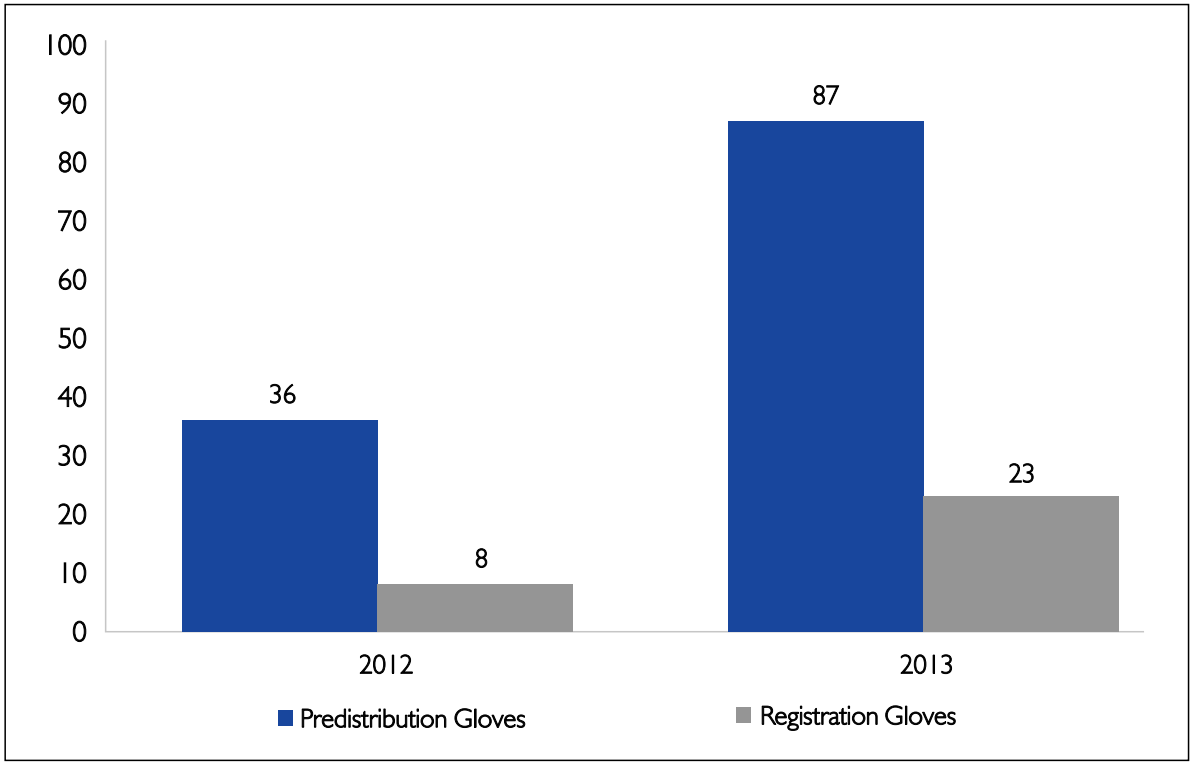


Figure 28: Gloves Samples Received For Analysis In The Medical Devices Laboratory

Resource Mobilisation Activities

- In 2012 the Microbiology laboratory received equipment from the UNDP Global Fund Round 8. Equipment received included an incubator, 2 autoclaves, 1 ultra-low (-80°C) freezer, 1 by 6 place manifold filtration unit and pump, 1 centrifuge and 1 microbalance. This improved a lot of the processes that had become bottlenecks in the analysis of products.
- The National Aids Council (NAC) will be funding the procurement of state of the art condom testing equipment from Enersol Australia. NAC will sponsor the supply, installation and commissioning of condom testing equipment for the Medical Devices Laboratory. The equipment is scheduled to be delivered mid-2014.
- The list included automated dimensions tester for length and width, 2 digital thickness testers, 2 sets of 6 head air inflation testers, 2 ultra-fast conductivity leak testers , 1 wet package seal integrity tester, and a compressor.
- The equipment to be supplied by Enersol will exclude computers so NAC also has expressed interest in purchasing 8 computers and printers as part of the equipment.

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