MCAZ

Medicines Control Authority of Zimbabwe





Annual Report 2011

MCAZ

Medicines Control Authority of Zimbabwe

Vision

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

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.

Core

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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Reports

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 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 manufacturing, 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 of Psychotropic Substances 1971
- The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1998.

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Chairperson's Statement

The Authority's activities were guided by the medium term strategic plan (2011 to 2013), which the Authority is committed to. During the first year of implementation of this three year plan, the Authority noted that there have been visible achievements already. Notable is the area of competent implementation of the statutes, with the successful implementation of the Import and Export Regulations. There are also many other achievements, which I cannot expound upon at this time. However, I urge management and staff to remain focused and continue working towards fulfilling the Authority's mandate.

The concept of risk management was introduced to the Authority, and efforts began to draw up a risk management policy.

I am honoured to report on the affairs of the Authority for the year 2011.

The year 2011 was fraught with numerous challenges, notably staff attrition that saw a number of experienced officers leaving the organization. The attention of both management and Authority was often drawn away from strategic issues to issues of recruitment and other distractions. However, during the year the Authority realized positive revenue inflows from traditional sources as well as from development partners supporting the Ministry of Health and Child Welfare in ensuring access to quality medicines. This enabled the Authority to end the year in a slightly better financial position than had been anticipated.

On the corporate governance front the Authority saw the positive effects of establishing an Audit Committee, which provides oversight over the Authority's operations. The efforts of the Audit Committee led to the adoption and implementation of important procedures; mainly the Finance and Administration Policy Manual. The introduction of the Procurement Committee at MCAZ, enabled the MCAZ to become fully compliant with provisions of the Procurement Act in its procurement processes. Authority members together with management attended a corporate governance seminar that clearly spelt out our different roles, giving us an opportunity to reflect on our own procedures with a view to improving them. The concept of risk management was introduced to the Authority, and efforts began to draw up a risk management policy. It is our hope that these new processes and policies will result in the Authority becoming a beacon of operational efficiency amongst the regulatory agencies in Zimbabwe and the region.

The year 2011 also saw the introduction of the Human Resources Committee to specifically focus on the Authority's most important internal customer, staff members. The issue of Committee and Board appraisals was put on the agenda for appropriate systems to be developed.

The Authority's activities were guided by the medium term strategic plan (2011 to 2013), which the Authority is committed to. During the first year of implementation of this three year plan, the Authority noted that there have been visible achievements already. Notable is the area of competent implementation of the statutes, with the successful implementation of the Import and Export Regulations. There are also many other achievements, which I cannot expound upon at this time. However, I urge management and staff to remain focused and continue working towards fulfilling the Authority's mandate.

I will conclude this statement by once again expressing the Authority's gratitude to the development partners particularly the UNDP and UNICEF as well as the Ministry of Health and Child Welfare, without whose support, we would have fallen short in the execution of our mandate. Their help has enabled us to better deliver services to our customers and to carry out projects that required significant funding. The Authority and the people of Zimbabwe, our primary stakeholders, are truly grateful for their invaluable and generous support.

We encourage all our stakeholders to rally behind the Authority in its efforts to ensure that accessible medicines and medical devices are of good quality, safety and efficacy.

Mrs. J. Ncube
Acting Chairperson

Director-General's Statement

In the short to medium term the Authority is eying WHO Prequalification of the laboratories and enforcement of complementary medicines regulation once approved by the Minister. Clock start and clock stop systems will also be implemented to ensure that Authority's time to registration excludes time spent waiting for responses from applicants. Gradual decentralisation and establishing permanent presence at all key ports of entry of medicines will occur in the long term. SADC joint inspections and joint reviews, as well as establishment of centres of regulatory excellence are anticipated in the medium to long term. The authority is committed to networking and collaboration with other regional and international regulatory bodies.

G. N. Mahlangu | Acting Director-General

This is the second annual report published by the Authority in accordance with the State Enterprises and Parastatals (SEP) Corporate Governance Framework (CGF) adopted by the Government of Zimbabwe. It also addresses some of the key requirements of the King III Code on Corporate Governance and the International Financial Reporting Standards (IFRPS). The Authority is striving to make this a tool for reporting its activities and hopefully to get feedback from stakeholders. This process will not only fulfil our obligations in terms of the relevant statutes, but will also bolster our efforts at improving service delivery.

In 2011 we managed to work down the backlog in applications for registration from 1000 in January 2011 to 300 in December 2011 and had manageable numbers by the time we came to close the year. This we hope will have the effect of encouraging more submissions for registration. The effective management of applications for registration requires that evaluators become prudent in the adoption of new requirements and ensure these requirements are communicated effectively. This was extensively discussed at a WHO International Training Workshop on Quality Documentation of Generic Medicines in the common technical documentation (CTD) format CTD, held in Harare in February 2011 by WHO and MCAZ.

The year 2011 saw the successful implementation of the import and export regulations for precursor chemicals. The Licensing and Enforcement unit was able to engage the other border control authorities through a series of meetings and seminars to sensitise them to the existing import and export control regulations. Stakeholders were also notified through the press and individual contact after notifications came through our systems notifying of their intention to import these controlled substances.

With respect to medicines, control of importation has revealed the extent of failure to comply with MCAZ labelling requirements by manufacturers. Whilst concessions were granted in the interest of accessibility of medicines, importations that continue to be non-compliant will be treated as unregistered at point of importation.

The year 2011 also saw the Laboratory Services unit and the Medical Devices unit celebrating their first anniversary of ISO 17025 accreditation, whilst the Legal unit under the guidance of the Legal Committee has been working on Medical Devices Regulations and Complementary Medicines Regulations so that the Authority can begin regulating these products, in accordance with best regulatory practice.

The units regularly reported to their Committees their progress on turnaround times and outputs, for purposes of monitoring.

The year 2011 saw the close collaboration between MCAZ, Ministry of Health and Child Welfare and UNICEF in ensuring improved accessibility of safe, effective, good quality and affordable essential medicines for child and maternal health. The Authority developed proposals for implementation of a quality assurance system that ensured that medicines procured through UNICEF were safe, effective and of good quality. The proposals included sampling and testing of medicines and

monitoring the supply chain for integrity and adherence to good distribution practices (GDP). Training and stakeholder consultations were also supported for capacity-building and sustainability of the improved system. UNICEF then agreed to make funding of $250 000 available to the Authority through the Essential Drugs Support programme. The Authority is grateful to UNICEF for this assistance, which has enabled us to undertake routine monitoring activities that would otherwise have been constrained by lack of resources.

Other important alliances were established during the year with the UNFPA, amongst others. These partners assisted us in our training and awareness activities. The Pharmacovigilance and Clinical Trials (PVCT) Unit introduced targeted spontaneous Adverse Event Reporting (ADR) for anti-malarial medicines, rolling out the programme in 84 sites located in five provinces. The programme was a success story due to the close collaboration with the National Malaria Control Programme in the Ministry of Health and Child Welfare. The results that will come out of this will inform the Authority on the best approach to safety monitoring. Significant funding from UNICEF and other development partners was attracted by the PVCT unit to support electronic data processing.

The authority maintained close ties with WHO in various international programmes such as prequalification of medicines and regulatory strengthening based on institutional development planning and follow up by Immunisation Vaccines and Biologics (IVB).

In our efforts to be transparent and visible, a number of articles were published in the print media as well as a number of interviews on both the radio and television. The editors of the print media and other journalists were hosted to a luncheon in an effort to build better relations with the press. Other stakeholder consultations both formal and informal were held to address issues of concern to the various parties, but also to clearly communicate the Authority's position on a number of issues.

The continued support and dedication of non-executive board, The Authority and Committee members, has been instrumental in guiding the activities of the various operational units. Managers continue to keep their ears to the ground and seeking funding opportunities to support the activities of their units and those of the Authority.
Our failure to retain competent staff in whom we would have invested considerably in terms of training made it difficult for us to deliver on the timelines for some of the unit plans. It is imperative that we continuously strive to improve our conditions of service as resources improve.

The support of both the members, the staff, the development partners and the Ministry is greatly appreciated.

Financially, 2011 was modestly better than 2010. Units managed to collect statutory fees within reasonable periods as the industrial sector began to experience a little stability. This year has seen some growth in the revenues from statutory sources as well as the partners who have supported a number of the Authority's activities. Expenditures were generally kept within budget as managers began using their commitment registers as a tool

Director-General's Statement (continued)

for managing expenditure. It was a learning year for most of them and as time progresses they will inevitably get better at projecting their budgetary requirements and understanding what should be covered by their budgets.

The Authority started accepting one hard copy and soft copy of the dossier on electronic storage media, instead of two hard copies. The use of intranet cut down the amount of paper used for internal communication between units. Management meetings shifted from paper-based agendas and minutes to electronic documents. Waste paper from committee meetings is shredded in-house and sent for recycling. Once the CTD guideline has been adopted the Authority would start working on a web-based electronic submission CTD dossiers (e-CTD). These small steps in addressing 'green issues' will go a long way in reducing the Authority's carbon footprint.

In the short to medium term the Authority is eying WHO Prequalification of the laboratories and enforcement of complementary medicines regulation once approved by the Minister. Clock start and clock stop systems will also be implemented to ensure that Authority's time to registration excludes time spent waiting for responses from applicants. Gradual decentralisation and establishing permanent presence at all key ports of entry of medicines will occur in the long term. SADC joint inspections and joint reviews, as well as establishment of centres of regulatory excellence are anticipated in the medium to long term. The authority is committed to networking and collaboration with other regional and international regulatory bodies.

G. N. Mahlangu
Acting Director-General

MCAZ Protecting your right to quality medicines ar

nd medical devices

Corporate Governance

The Medicines Control Authority of Zimbabwe (the Authority) values the importance of good corporate governance principles as these have an impact on the operations of the organisation and how it is perceived by its stakeholders. To this end, the Authority follows the guidance from the State Parastatals Corporate Governance Framework(CGF) , The King III Report, The MCAZ Act Chapter(15.03), the Public Finance Management Act, International Financial Reporting Standards(IFRS) among notable guidelines in practising good corporate governance.

The Authority is required by the CGF to produce annual audited financial statements. This has been accomplished over the years, although the 30 June deadline was not met for the 2011 financial statements.

The Board

The Board, also known as the Authority, is appointed by the Minister of Health and Child Welfare in terms of section 4 of the Medicines and Allied Substance Control Act(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(Chief Executive) is the head of the Secretariat. The board meets at least quarterly every year. At any given time the Authority consists of not less than eight and not more than twelve members determined by the Minister subject to subsection (2) of section 4 of the MASCA.

As at 31 December 31 2011, the composition of the Authority was as follows;

MEMBER	SECTION UNDER WHICH APPOINTMENT IS MADE	DATE APPOINTED	TERMINATION
DR E.S Mazhindu(Chairman)	Section 4(1) (any other)	01/09/2007	31/08/2012
Mrs J. Ncube (Vice Chairperson)	Section 4(2)(e) (Law Society)	01/04/2011	31/03/2014
Dr. A. F. Zinanga	Section 4(2)(a) (Medical Association)	31/07/2011	31/03/2014
Dr. P. Muvavarirwa	Section 4(2)(b) (Council of Vet. Surgeons)	01/04/2011	31/03/2014
Mrs J. Chaibva	Section)4(2)(c) (Pharmaceutical Society	01/04/2011	31/03/2014
Dr. P Chonzi	Section 4(2)(d) (Local Authority)	31/08/2011	31/03/2014
Dr. R. Gwisai	Section 4 (2)(f) (Specialist Physician)	31/07/2011	31/03/2014
Dr. T. R. Bwakura	Section 4(2)(g) (knowledge of action & application of medicines)	31/07/2011	31/03/2014
Mrs R. Hove	Section 4(2) (h) (Ministry of Health)	01/04/2011	31/03/2014
Dr. C. C. Maponga	Section 4(1) (Any other)	28/07/2011	31/03/2014
Mrs. F. N. Sifeku	Section 4(1) (Any other)	01/04/2011	31/03/2014
Mrs. D. Mandaza	Legal Adviser	31/08/2011	31/03/2014

BOARD AND COMMITTEE ATTENDANCE (FROM 1 JANUARY TO 31 DECEMBER 2011)

NAME OF MEMBER	AUTHORITY		AUDIT COMMITTEE		HR COMMITTEE		FINANCE COMMITTEE	
	ATTENDED	POSSIBLE	ATTENDED	POSSIBLE	ATTENDED	POSSIBLE	ATTENDED	POSSIBLE
Dr. E. S Mazhindu	3	4					10	12
Mrs. J. Ncube	2	3			3	3		
Dr. A. F. Zinanga	2	2					9	12
Dr. P Muvavarirwa	4	4	3	4	3	3	11	12
Mrs J. Chaibva	2	3						
Dr. P. Chonzi	3	3	4	4	1	3		
Dr. R. Gwisai	4	4			2	3		
Dr. T. R. Bwakura	1	2						
Mrs. R. Hove	2	3						
Dr. C. C. Maponga	2	2			3	3	8	12
Mrs. F. N. Sifeku	4	4			1	3		
Mrs. D. Mandaza	4	4						
Mr. C. F. Dube			3	4				
Mr. F. Gwiza			3	3				
Mr. M. Chitiki			1	4				
Mr. E. Jinda					2	3		
Mrs. S. Gono							4	4
Mr. J. B. Nderere							6	12
Mr. E.C. Mbadza							9	12

Overally the board attendance rate was good and in sufficient numbers to form a quorum. This also ensured that, there was sufficient debate to enable matters to be discussed with finality.

The role of the board is to provide strategy guidance on the operations of the Authority and to ensure that effective controls are in place. For the better exercise of its functions and powers the Authority has put in place a number of committees all of which are guided by specific approved terms of reference. All of the committees are chaired by a member of the main board(Authority).

Audit Committee

The committee is responsible for reviewing internal controls, including the scope of the internal audit programme, the internal and external audit findings as well as recommending the appropriate action to be taken by the responsible officers. The committee also reviews the financial reporting aspects of the Authority and ensures that accounts are prepared in a timely and accurate manner. The Audit Committee also meets with the Authority's External Auditors to discuss their report as well as their assessment of the relative strengths and weaknesses of key control areas.

Risk Management

The Audit Committee also reviews the effectiveness of the Authority's risk management process. As a matter of principle an appropriate Enterprise Risk Management Framework which guides the risk management process was approved in 2011. The main objective of the Risk management framework is to ensure that risk management is embedded in all the Authority's processes whilst at the same time delegating the authority to mitigate these risks by those with knowledge and experience of how to mitigate them. Pursuant to this, consolidated

Corporate Governance (continued)

Authority risk reports are discussed at the committee's quarterly meetings where the committee also assesses the effectiveness of the mitigating strategies put in place. The high risks are then escalated to the main board in compliance with the Risk Framework.

Human Recourses 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

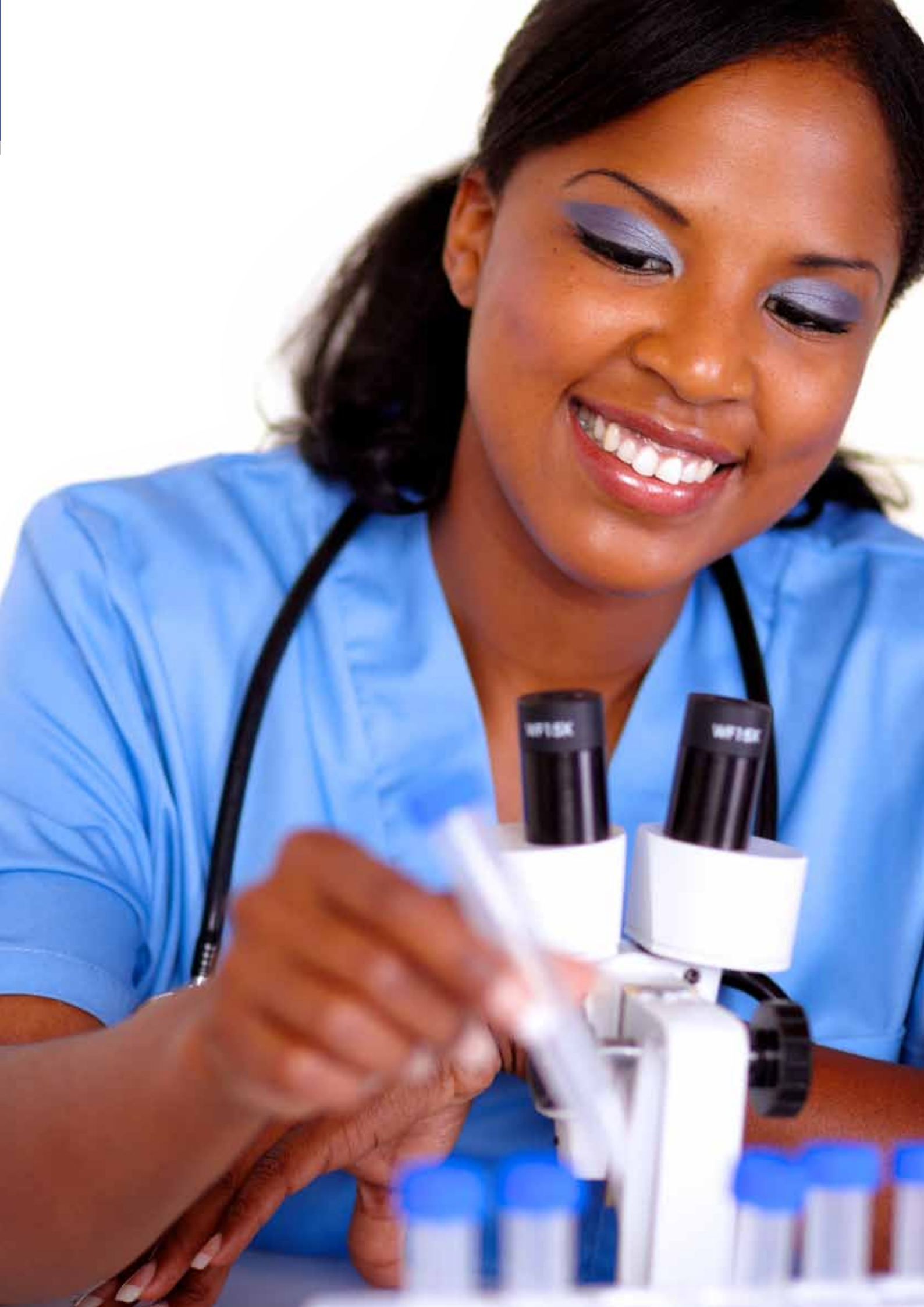
The Authority is required to maintain adequate accounting records and prepare financial statements according to generally accepted accounting standards. The committee which helps the Authority achieve this is the Finance Committee, which sits monthly to review the management accounts. The committee also reviews the annual operating and capital income and expenditure budgets and recommends approval by the Authority. The committee also reviews financial policies and principles.

MANAGEMENT

NAME	POSITION
Ms. G. N. Mahlangu	Acting Director- General
Mr. S. Chamisa	Finance Director
Dr.W. Wekwete	Assistant Director- Evaluation & Registration
Mr. R. Rukwata	Assistant Director- Legal & Corporate Affairs
Mrs. S. D. Dube- Mwedzi	Assistant Director- Licensing & Enforcement
Mrs. P. P. Nyambayo	Assistant Director- Pharmacogilance and Clinical Trials
Mrs. B. Dube	Assistant Director- Laboratory Services
Mr. E.K. Kulube	Finance Manager
Mr.P. N. Ndanga	Quality Manager
Mr.T. Gonho	Manager- Medical Devices
Mrs. T.E. Mberi	Human Resources and Admin Manager
Mrs. M. A. Maunga	Legal Manager
Ms. S. Buwu	Internal Auditor

Corporate Social Responsibility.

The Authority has a provision for sponsoring third and fourth year pharmacy undergraduates from the University of Zimbabwe. As of 2011 eight (8) students had benefited from this programme since its inception in 2007.



REPORT OF THE COMPTROLLER AND AUDITOR-GENERAL

TO THE MINISTER OF HEALTH & CHILD WELFARE AND THE BOARD OF DIRECTORS IN RESPECT OF THE FINANCIAL STATEMENTS OF MEDICINES CONTROL AUTHORITY OF ZIMBABWE FOR THE YEAR ENDED DECEMBER 31, 2011.

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, 2011, and the statement of 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 3 to19.

Management'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 International Standards on Auditing. Those Standards require that I comply with ethical requirements and plan and perform the audit to obtain reasonable assurance whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the 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, 2011, its financial performance and 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 been properly prepared in compliance with the disclosure requirements of the Medicines and Allied Substances Control Act (Chapter 15:03) and relevant Statutory Instruments.

M. CHIRI
COMPTROLLER AND AUDITOR - GENERAL
October 29 2012

Statement of Financial Position

as at December 31, 2011

	Notes	Historical cost 2011 US$	Historical cost 2010 US$
ASSETS			
Non-Current Assets		**4,418,225**	**4,885,549**
Property, plant and equipment	4	2,728,880	3,001,039
Investment properties	5	1,470,750	1,884,510
Available-for-sale investment	6	218,595	-
Current Assets		**631,246**	**364,030**
Inventory	7	15,591	12,972
Trade receivables	8	147,591	124,956
Other receivables	9	127,805	95,178
Cash and cash equivalents	10	340,259	130,924
Total Assets		**5,049,471**	**5,249,579**
RESERVES AND LIABILITIES			
Reserves		**4,600,299**	**4,944,559**
Capital Reserve		5,234,444	5,234,444
Retained Earnings		(634,145)	(289,885)
		85,857	**65,968**
Deferred income	11	85,857	65,968
Current Liabilities		**363,315**	**239,052**
Trade payables	12	13,429	15,424
Other payables	13	261,617	138,750
Leave pay provision	14	88,269	84,878
Total Reserves and Liabilities		**5,049,471**	**5,249,579**

G.N.Mahlangu
(Director-General).
2012

J. Ncube
(Acting Chairman)
2012

Statement of Comprehensive Income

for the year ended December 31, 2011

	Notes	2011 US$	2010 US$
INCOME		**2,252,823**	**2,067,037**
Deferred income	11	9,856	6,999
Rental and interest income	15	109,706	102,371
Medicines control income	16	1,849,724	1,710,072
Laboratory services	17	210,455	216,549
Donations		72,972	-
Profit on disposal of property,plant and equipment		-	18,372
Other Income		110	12,674
EXPENDITURE		**2,557,075**	**2,169,755**
Employee benefits	18	1,467,442	1,269,283
Administration Expenses	19	1,050,854	900,472
Loss on disposal of property,plant and equipment		38,779	-
Deficit for the year		**(304,252)**	**(102,718)**
Other comprehensive income		-	-
Total compehensive income		**(304,252)**	**(102,718)**

Statement of Changes in Equity

for the year ended December 31 , 2011

	Retained Earnings US$	Capital Reserve US$	Total US$
Balance as at January 1,2010	**(187,167)**	**-**	**(187,167)**
Transfer to Accumulated fund	-	5,234,444	5,234,444
Deficit for the year	(102,718)	-	(102,718)
Closing balance at December 31, 2010	**(289,885)**	**5,234,444**	**4,944,559**
Prior year Adjustment	(40,008)	-	(40,008)
Restated Opening Balance	**(329,893)**	**5,234,444**	**4,904,551**
Deficit for the year	(304,252)	-	(304,252)
Balance as at December 31,2011	**(634,145)**	**5,234,444**	**4,600,299**

Statement of Cash Flows

for the year ended December 31, 2011

	Notes	Historical cost 2011 US$	2010 US$
Net Cash flow from Operating Activities		**241,380**	**36,658**
Deficit for the year		(304,252)	(102,718)
Adjusted for :		**482,641**	**286,116**
Depreciation	5b	334,062	301,203
Increase in provision for leave pay		3,391	17,645
Pension Adjustment		151,905	-
Deferred income	11	(9,856)	(6,999)
Loss/(Profit) on disposal of property, plant and equipment		38,781	(18,372)
Sundries reversals		(17,837)	-
Interest received		(17,805)	(7,361)
Working capital changes:		**62,991**	**(146,740)**
Increase in inventory		(2,619)	-
Increase in trade receivables		(22,635)	(67,515)
Increase in other receivables		(32,627)	(86,880)
Decrease in payables		(1,995)	(18,158)
Increase in other payables		122,867	25,813
Net Cash Flow from Investing Activities:		**(32,045)**	**(118,833)**
Purchase of property, plant and equipment		(59,162)	(145,194)
Proceeds from Disposal of property, plant and equipment		9,312	19,000
Interest received		17,805	7,361
Net Increase/decrease in cash and cash equivalents		**209,335**	**(82,175)**
Cash and Cash Equivalents at beginning of the year		**130,924**	**213,099**
Cash and Cash Equivalents at year end	**10**	**340,259**	**130,924**

Notes to the Financial Statements for the year ended December 31, 2011

1. REPORTING ENTITY 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 first of August1997. 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, 2011, 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, 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 fair value;
- Property, Plant and Equipment 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 zero.

Notes to the Financial Statements for the year ended December 31, 2011

2.5 New and revised standards and interpretations

2.5.1 Adopted new standards, interpretations and amendments effective from January 2011

i. Revised IAS 24, ' Related party disclosures' issued in November 2009:

It supersedes IAS 24, 'Related party disclosures' issued in 2003. IAS 24 (revised) is mandatory for periods beginning on or after January 2011. Earlier application, in whole or in part, is permitted. The revised standard clarifies and simplifies the definition of a related party and removes the requirement for government-related entities to disclose details of all transactions with the government and other government related entities.

ii. IAS 1(amendment) Presentation of financial statements

The amendment clarifies that the potential settlement of a liability by the issue of equity is not relevant to its classification as current and non-current. By amending the definition of current liability, the amendment permits a liability to be classified as non- current (provided that the entity has an unconditional right to defer settlement by transfer of cash or other assets for at least 12 months after the accounting period).

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, 2010.

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.

Notes to the Financial Statements for the year ended December 31, 2011

The rates applied per annum are as follows:

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

3.I.3. 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 at cost on initial recognition and subsequently at fair value with any change therein recognized in profit or loss.

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. Donations

Donations related to assets, including non-monetary donations 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 be reasonably have value placed upon them and transactions with government which cannot be distinguished from the normal trading other entity.

Notes to the Financial Statements for the year ended December 31, 2011

Donations related to income are credited to the statement of comprehensive income.

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

3.3. Financial Instruments

3.3.1. Financial assets

The Authority classifies financial assets into the following categories:

- Financial asset at fair value through profit or loss
- Held to maturity financial assets
- Loans and receivables
- Available- for –sale financial assets.

3.3.1.1. Fair value through profit or loss

A financial asset is classified as fair value through profit or loss if it is classified as held for trading or designated as such on initial recognition. Financial assets are designated as at fair value through profit or loss if the Authority manages such investments and makes purchases and sale decisions based on their fair value in accordance with the Authority's documented risk management or investment strategy. Attributable transaction costs are recognised in profit or loss as incurred. Financial assets at fair value through profit or loss are measured at fair value and changes therein, which takes into account any dividend income, are recognised in profit or loss.

3.3.1.2. Held –to- maturity financial assets

If the Authority has the positive intent and ability to hold debt securities to maturity, then such financial assets are classified as held- to- maturity. Held -to- maturity financial assets are recognised initially at fair value plus any directly attributable transaction costs. Subsequent to initial recognition, held –to- maturity financial assets are measured at amortised cost using the effective interest method, less any impairment losses.

3.3.1.3. Loans and receivables

Loans and receivables are financial assets with fixed or determinable payments that are not quoted in an active market. Such assets are recognised initially at fair value plus any directly attributable transaction costs. Subsequent to initial recognition, loans and receivables are measured at amortised cost using the effective interest method, less any impairment losses.

Loans and receivables comprise cash and cash equivalents and trade and other receivables.

3.3.1.4. Available- for- sale financial assets

Available- for- sale financial assets are non-derivative financial assets that are designated as available

Notes to the Financial Statements for the year ended December 31, 2011

for sale or are not classified in any of the above categories of financial assets. Available –for-sale financial assets are recognized initially at fair value plus any directly attributable transaction costs.

Subsequent to initial recognition, they are measured at fair value and changes therein, other than impairment losses and foreign currency differences on available- for- sale debt instruments are recognized in other comprehensive income and presented in the fair value reserve in equity. When an investment is derecognized, the gain or loss accumulated in equity is reclassified to profit or loss.

3.3.1.5. Cash and cash equivalents

Cash and cash equivalents comprise cash balances and call deposits with maturities of three months or less from acquisition date that are subject to a insignificant risk of changes in fair value, and are used by the Authority's in the management of its short term commitments.

3.4.1. Financial liabilities

3.4.2. 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 noncurrent 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 received 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.

Notes to the Financial Statements for the year ended December 31, 2011

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

4 PROPERTY,PLANT AND EQUIPMENT

	Land & Buildings US$	Plant & Machinery US$	Motor Vehicles US$	Computers & Equipment US$	Office Equipment US$	Furnitures & Fittings US$	Total US$
Adjusted Opening carrying amount 31.01.10	**1,745,250**	**1,058,656**	**111,042**	**43,866**	**15,302**	**66,044**	**3,040,160**
Adjusted Deemed Cost	1,790,000	1,174,701	246,687	55,584	19,131	72,912	3,359,015
Adjusted Accumulated Depreciation	(44,750)	(116,045)	(135,645)	(11,718)	(3,829)	(6,868)	(318,855)
Additions/Deemed Cost	-	95,085	99,029	12,760	5,302	944	213,120
Disposals	-	-	(53,464)	-	-	-	(53,464)
Depreciation for the year	(44,750)	(125,127)	(52,788)	(16,146)	(5,465)	(7,337)	(251,613)
Depreciation on disposals			52,836				52,836
Closing carrying amount 31.12.10	**1,700,500**	**1,028,614**	**156,655**	**40,480**	**15,139**	**59,651**	**3,001,039**
Cost	1,790,000	1,269,786	292,252	68,344	24,433	73,856	3,518,671
Accumulated Depreciation	(89,500)	(241,172)	(135,597)	(27,864)	(9,294)	(14,205)	(517,632)
Prior Year Adjustment							
Deemed Cost	3,600	-	-		(50)	-	3,550
Accumulated Depreciation	(68)	5	(22,207)	(65)	25	96	(22,214)
Adjusted opening carrying amount 01.01.11	**1,704,032**	**1,028,619**	**134,448**	**40,415**	**15,114**	**59,747**	**2,982,375**
Adjusted Deemed Cost	1,793,600	1,269,786	292,252	68,344	24,383	73,856	3,522,221
Adjusted Accumulated Depreciation	(89,568)	(241,167)	(157,804)	(27,929)	(9,269)	(14,109)	(539,846)
Additions/Deemed Cost	-	4,181	19,347	10,397	21,504	3,733	59,162
Donations				29,745			29,745
Disposals	-	(64,110)	(59,265)	(6,646)	(500)	-	(130,521)
Depreciation for the year	(44,840)	(127,005)	(87,159)	(20,188)	(7,503)	(7,617)	(294,312)
Depreciation on disposals	-	19,124	58,824	4,150	333	-	82,431
Closing Carrying Amount 31.12 11	**1,659,192**	**860,809**	**66,195**	**57,873**	**28,948**	**55,863**	**2,728,880**
Deemed Cost	1,793,600	1,209,857	252,334	101,840	45,387	77,589	3,480,607
Accumulated Depreciation	(134,408)	(349,048)	(186,139)	(43,967)	(16,439)	(21,726)	(751,727)

Notes to the Financial Statements for the year ended December 31, 2011

		Note	Historical cost 31.012.11 US$	Historical cost 12.1.2010 US$
5	**INVESTMENT PROPERTY**			
	Opening carrying amount		**1,884,510**	**1,930,500**
	Deemed Cost		1,983,600	1,980,000
	Accumulated Depreciation		(99,090)	(49,500)
	Prior year Adjustment			
	Deemed cost		(3,600)	-
	Accumulated Depreciation		90	-
	Adjusted Opening Carrying Amount		**1,881,000**	**-**
	Deemed Cost		1,980,000	-
	Accumulated Depreciation		(99,000)	-
	Additions		-	3,600
	Disposals		(390,000)	-
	Depreciation for desposal		19,500	-
	Depreciation for the year		(39,750)	(49,590)
	Closing carrying amount		**1,470,750**	**1,884,510**
	Cost		1,590,000	1,983,600
	Accumulated Depreciation		(119,250)	(99,090)
5b	**Depreciation**			
	Property,Plant and Equipment	4	294,312	251,613
	Investmernt Property	5	39,750	49,590
			334,062	301,203

Notes to the Financial Statements for the year ended December 31, 2011

		Historical cost	
		2011	2010
		US$	US$
6	**Investment in other companies**		
	Available -for-sale investment	218,595	-
		218,595	**-**
7	**Inventory**		
	Stock of stationery	6,639	-
	Fuel stock	8,952	12,972
		15,591	12,972
8	**Trade receivables**	147,914	124,956
		147,591	**124,956**
9	**Other receivables**		
	Sundry receivables	86,301	81,302
	Prepayments/deferred expenditure	3,268	8,656
	Rentals	34,460	-
	Staff debtors	3,776	20,895
	Provision for doubtful debts	-	(15,675)
		127,805	**95,178**
10	**Cash and cash equivalents**		
	Cash and bank	226,189	77,017
	Short term investments	114,070	53,907
		340,259	**130,924**
11	**Deferred income**		
	Opening Carrying Amount	65,968	1,440
	Additions of donated equipment	29,745	71,527
	Ammortisation for the year	(9,856)	(6,999)
	Closing Carrying Amount	**85,857**	**65,968**

Notes to the Financial Statements for the year ended December 31, 2011

		Historical cost	
		2011 US$	2010 US$
12	**Trade payables**	**13,429**	**15,424**
13	**Other payables**		
	Sundry payables	125,205	57,018
	Unallocated income	107,932	65,752
	Audit fees	28,480	15,980
		261,617	**138,750**
14	**Leave pay provision**	88,269	84,878
		88,269	**84,878**
15	**Investment income**		
	Rentals	91,901	95,010
	Interest earned	17,805	7,361
		109,706	**102,371**
16	**Medicines control income**		
	Amendment Fees	38,695	45,905
	Clinical Trials	11,520	14,160
	Drug registration and forensic Examination	18,745	20,946
	Import and Export Licenses	143,382	52,576
	Inspection	137,301	119,494
	Dangerous Drug License	4,170	7,120
	Persons and Premises Licenses	101,195	125,695
	Registration Fees	302,262	176,469
	Renewal of Licenses	219,055	236,729
	Retention Fees	595,249	659,286
	Sales representatives and Wholesale Dealers	205,905	191,520
	Other Income	3,250	17,637
	Training Medicines	8,750	6,350
	Unregistered Medicines	42,695	29,635
	Veterinary Permits	17,550	6,550
		1,849,724	**1,710,072**
17	**Laboratory services**		
	Condom Testing	63,585	54,221
	Glove Testing	8,490	16,555
	Medical Devices-Registration	5,000	10,600
	Samples-External Clients	129,870	63,445
	Samples- Registration and Post Market Surveilance	200	71,129
	Sundry income	3,310	599
		210,455	**216,549**

Notes to the Financial Statements for the year ended December 31, 2011

		Historical cost	
		2011 US$	2010 US$
18	**Employee benefits**		
	Directors' Expenses	11,560	15,260
	Other Staff Costs	-	1,115
	Pension and Medical Aid	321,925	161,051
	Salaries and Wages	1,047,939	1,000,528
	Staff Recuitment	8,672	1,119
	Staff Training Expenses	6,261	8,244
	Staff Welfare	9,826	14,940
		1,406,183	**1,202,257**
	Compensation for key management		
	Meeting Allowances	43,761	54,474
	Meeting expenses	14,462	11,298
	Board meeting expenses	3,036	1,254
		61,259	**67,026**
	Total employee benefits	**1,467,442**	**1,269,283**
19	**Administration expenses**		
	Audit fees	12,500	7,200
	Bank charges	11,547	11,819
	Communications	44,506	40,721
	Consumables	29,690	27,284
	Fines	1,357	-
	General administration	25,082	21,654
	Inspections	97,291	-
	Investment property expenses	35,770	16,290
	IT expenses	6,152	7,013
	Legal and Professional fees	90,935	51,379
	Printing and Stationery	38,257	27,125
	Project expenses	35,943	-
	Provision for leave pay	3,391	17,645
	Public relations	5,023	24,350
	Quality assurance costs	7,632	10,765
	Rates, Electricity and Water	2,605	8,550
	Repairs and Maintenance	45,728	37,441
	Security and Insurance costs	13,523	7,852
	Strategic planning	15,999	8,392
	Subscriptions	1,601	7,260
	Depreciation5b	334,062	301,203
	Travelling and Subsistence	40,297	129,518
	Vehicle running costs	151,963	137,011
		1,050,854	**900,472**

BUSINESS STATISTICS

Companies with an MCAZ premises licence or permit	681
Local Manufacturers of medicinal products	13
Pharmaceutical Wholesale dealers or distributors	67
Pharmacies	315
Section 75 Authorisations	2758
Import permits	1042
Licenses for psychotropic substances and narcotics	119

INVENTORY OF PRODUCT REGISTRATIONS BY TYPE OF PRODUCT AT THE END OF 2011

Human and veterinary medicinal products (original, generic, medicinal products)	1900
Human medicines	1589
Veterinary medicines	311
Antibiotics	237
Anti-hypertensive	57
ARVs	112
Oncology	36
Anti-TB	12
Anti-mycotic	44

MCAZ AS AN ORGANISATION

Staff headcount as at year-end	84
Number of full-time positions as at year-end	72
Technical Staff	73.8%
Non-technical staff	26.2%
Total women	47.6%
Total men	52.4%
Staff working part-time	3.6%
Contract staff	10.7%
Average staff age	29.2 years
Staff turnover rate	15.5%

Human Medicines

In order to acquire product registration of a medicinal product, an applicant has to submit all the documentation regarding its safety, efficacy and quality. The documentation is then evaluated to establish compliance with current scientific registration requirements. The registration process distinguishes between Innovator medicinal products and Generic medicinal products.

Activities

- In 2011,115 new applications for registration were submitted. Of these 115, 4 were new Chemical Entities and 111 were generic applications.

- A total of 58 applications were evaluated and registered in 2011. Of these registered products 14 were anti-retroviral drugs, 3 were anti-tubercular drugs, 6 antibiotics and 35 other drugs that fall into various classes. In addition 84 applications were refused registration due to failure to address registration requirements, while 42 previously cancelled applications were re-instated.

- 53 applications for complementary medicines were tabled before the Registration Committee for determination of registerability. 30 were deemed registerable for either making medicinal claims or containing medicinal ingredients. These applicants were advised to follow normal registration procedures. 23 were deemed not registerable and were given clearance to be marketed as complimentary medicines.

Figure 1: Human medicines processed in 2011 (Source: MCAZ Evaluations and Registrations December, 2011)

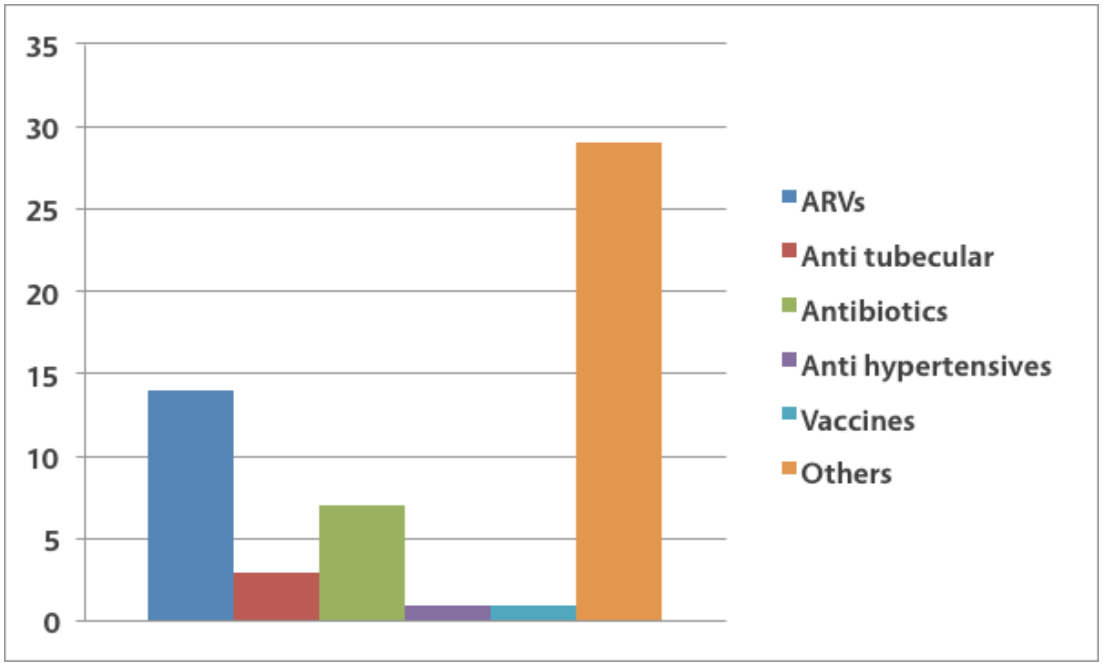


Figure 2: Products by type registered in 2011

Veterinary Medicines

A similar process is carried out for the registration of Veterinary medicines. An applicant has to submit all the documentation regarding its safety, efficacy and quality. The documentation is then evaluated to establish compliance with current scientific registration requirements.

Activities

- In 2011, 16 applications were submitted for registration of innovative and non-innovative medicinal products.

- 10 applications were registered, while 3 applications were withdrawn from the evaluation process by the applicants and 6 applications were refused registration due to failure to address registration requirements.

Evaluations and Registrations
(continued)

Figure 3: Veterinary medicines processed in 2011 (Source: MCAZ Evaluations and Registrations, December 2011)

Meetings with Customers

MCAZ holds meetings with applicants to clarify content and procedural issues (Presubmission Advice, Scientific Advice and Clarification Meetings) in the interest of efficiency and transparency of the authorisation procedures.

Activities

- In 2011, a total of 219 company meetings were held with applicants .These included clarification meetings, pre-submission meetings and technical advice meetings.

Registration Committee

A panel of experts supports MCAZ in assessment and provision of advice relating to the scientific evaluations of the registration documents for human medicinal products.

Activities

- During the course of its 12 meetings, the RC panel issued 184 recommendations on registration applications. These related in particular to new applications for registration of medicinal products or amendments of registered products.

- MCAZ has made developed terms of reference (TOR) for each expert committee on behalf of the Authority. The TORs was adapted from WHO guidelines and the Corporate Governance Framework for State Enterprises and Parastatals.

Special Activities and Events in the Registrations and Evaluations

WHO International Training Workshop on Quality Documentation of Generic Medicines in Common Technical Document (CTD) Format

The World Health Organisation (WHO/HQ/QMS) team organised an international training workshop on Quality Documentation of Generic Medicines in Common Technical Document (CTD) format in Harare at the Meikles Hotel from the 21st to 25th of February 2011. The workshop was designed for senior regulatory assessors and quality assurance or regulatory managers from pharmaceutical companies. The workshop focused on documentation of quality of final oral solid dosage forms of generic medicines. It was attended by participants from the SADC region ,MCAZ staff and representatives from the local pharmaceutical manufacturing community.

Labeling Requirements

A consultative meeting with industry representatives was held following the circular 3 of 2011 (Ref: B/279/35/3/2011) in which the Authority reminded applicants and principals that failure to comply with labelling requirements was a contravention of Section 37 of the Medicines and Allied Substances Control (General) Regulations (S.I 150 of 1991) as read with section 36 of the Medicines and Allied Substances Control Act [Chapter 15:03] and that products failing to meet conditions of registration were deemed unregistered.

Following representations from Industry, the Authority agreed to certain concessions which were calculated to allow time for full compliance of all products by the end of 2012. After this period, all registered products on the Zimbabwean market should comply with all conditions of registration.

Deregistration of Dextropropoxyphene

At its May meeting of 2011, the Registration Committee agreed to deregister all medicines containing dextropropoxyphene due to the risk of cardiac toxicity. This decision was made after a recommendation from the Adverse Drugs Reaction and Medicines Review Committee. Manufacturers of all dextropropoxyphene-containing medicines were informed of the new development and an alert notice to all health professionals was published on the website. The Committee emphasized the need to ensure that alternatives were available before the phasing out of dextropropoxyphene-containing medicines so that patients receiving the medication chronically did not suffer shortages.

Legal and Corporate Affairs

Activities

- The trend seen in recent years was that the number of final warnings issued have increased owing to the gravity of the offences committed which varied from selling unregistered and expired medicines and operating without the continuous supervision of a licensed pharmacist to poor record keeping of dangerous drugs.

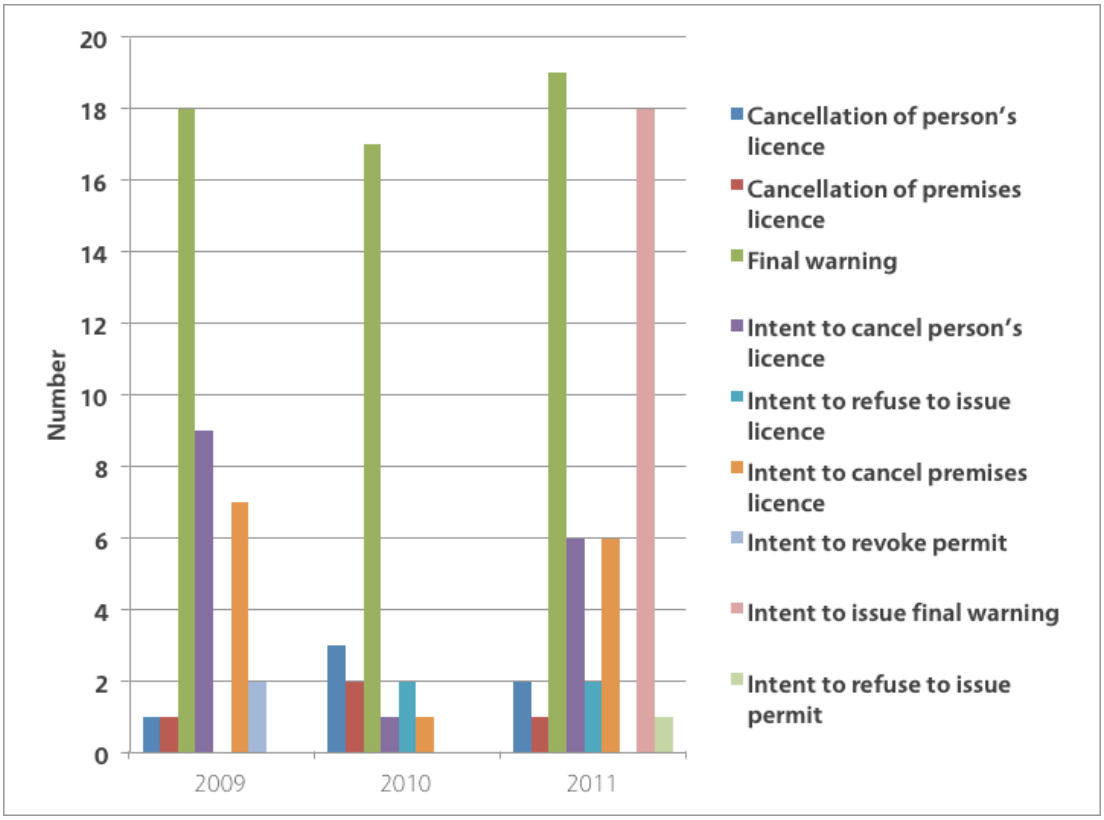


Figure 4: Authority's decisions on Licenses from 2009 to 2010 (Source: MCAZ Legal and Corporate Affairs December, 2011)

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 inspection.

Activities

- At the end of 2011, 681 companies held a premises licence for the manufacture, wholesale and dispense medicines. This represents an increase of 70 companies from the previous year.

- 125 premises licences were issued for the first time in 2011.

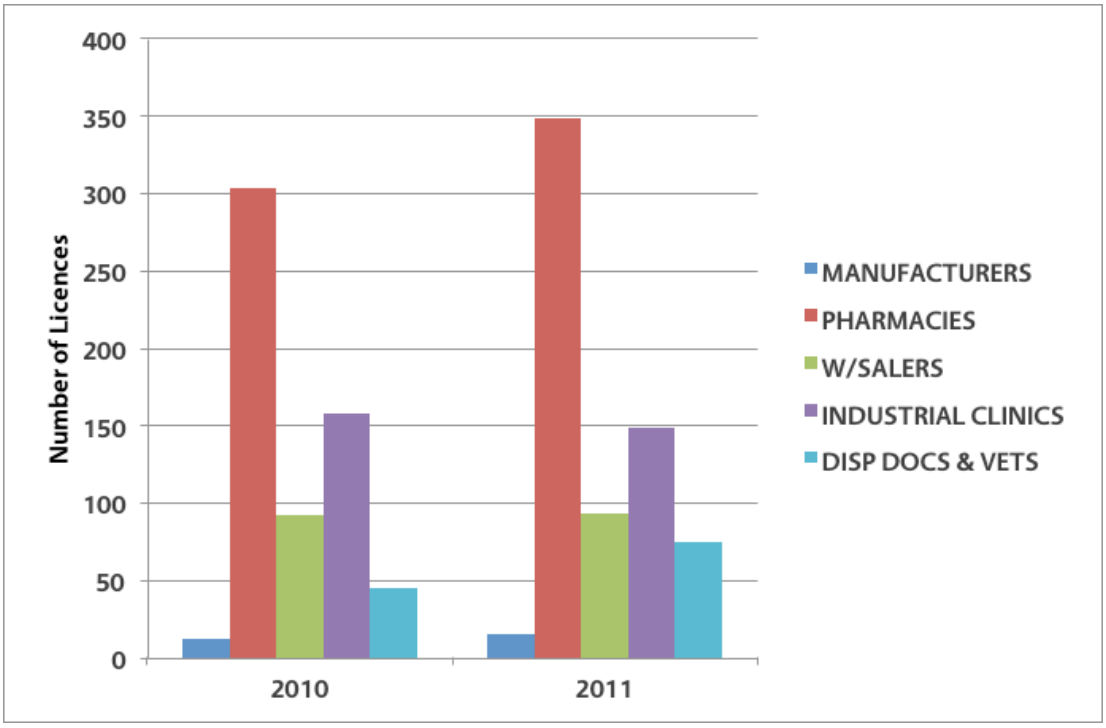


Figure 5: Premises Licences issued in 2011, New and Renewals. (Source: MCAZ Licensing and Enforcement December 2011)

Licensing and Enforcement
(continued)

PERSONS

On submission of an application, MCAZ will issue medical professionals (Pharmacists, Pharmacy Technicians, Medical Doctors, Veterinary Surgeons, Nurses and Sales representatives) a person's licence to dispense (or deal in) medicines.

Activities

- In 2011, 1016 professionals were licensed to dispense, and/or deal in medicines. This represents an increase of 194 professionals from the previous year.

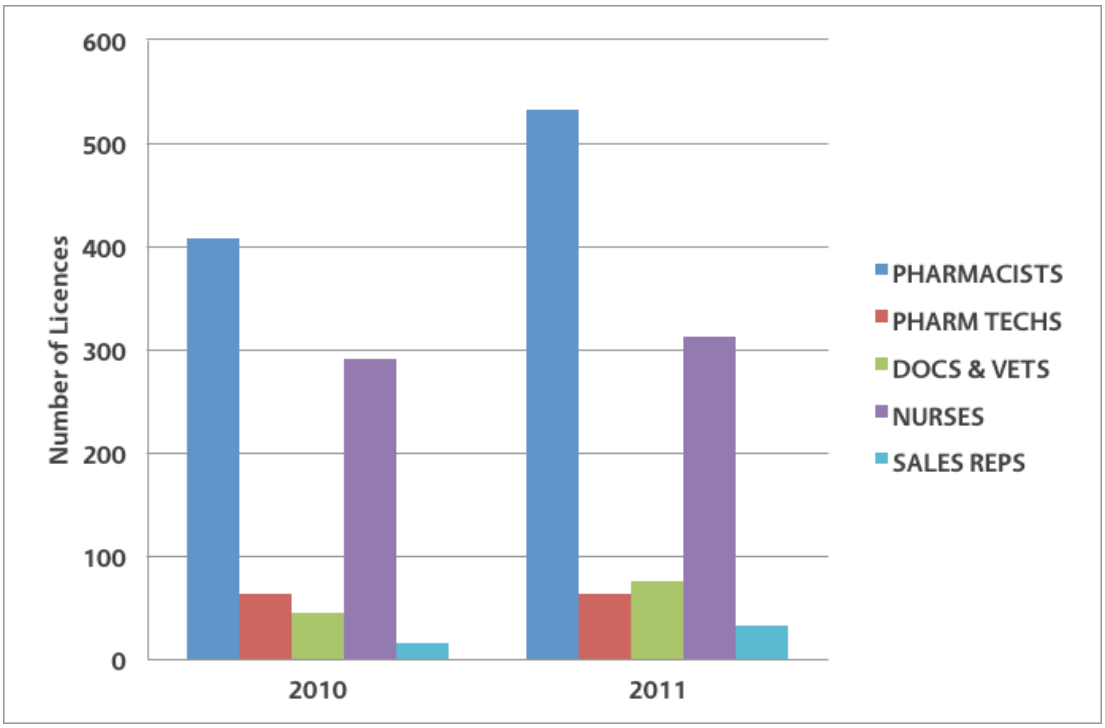


Figure 6: Persons licence issued by MCAZ, New and Renewals (Source: MCAZ Licensing and Enforcement December 2011)

SECTION 75 AUTHORISATIONS

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 practitioner 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.

Activities

- The number of section 75 applications processed in 2011 came to a total of 2758.

- 554 of the section 75 authorisations issued for human medicinal products came from institutions and 2204 were from individual prescriptions. Investigational products made up 35 of these authorisations.

IMPORT AND EXPORT CONTROL

On submission of an application, MCAZ will issue holders of a premises licence or permit a permit for importing or exporting registered medicinal products.

Activities

- In 2011, 1042 import permits were issued to premises licence/permit holders, mostly wholesalers.

CONTROL OF THE FLOW OF NARCOTICS

Zimbabwe is a signatory to the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, MCAZ being the body responsible for ensuring the monitoring and control of controlled substances such as narcotics (Dangerous Drugs) and 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). MCAZ therefore issues import, export and possession licences to companies who manufacture, procure or possess controlled substances.

Activities

- In 2011, 119 licenses to import narcotics and psychotropic substances were issued. 109 licenses to possess, acquire and administer narcotics were issued.

- MCAZ received a total of 119 notifications of national narcotic deliveries.

Licensing and Enforcement
(continued)

INSPECTIONS

MCAZ carries out inspections as prerequisites for issuing or maintaining a premises licence. Adherence to the quality standard GMP (Good Manufacturing Practices) is checked for the manufacturers of pharmaceutical products and/or the GDP (Good Distribution Practice) for wholesalers. The 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.

Activities

- A total of 460 inspections were carried out of all the licensed and approved premises, by the MCAZ Inspectorate
- MCAZ carried out 18 special investigational inspections.
- MCAZ also took part in inspections by partner organisations in 2011. MCAZ inspectors participated in international inspection programs: 1 inspection performed with WHO of a manufacturer of medicinal products in China, with the MCAZ Inspector being an observer.
- 3 staff from MCAZ took part in country assessment visits carried out as part of WHO teams in 3 countries.

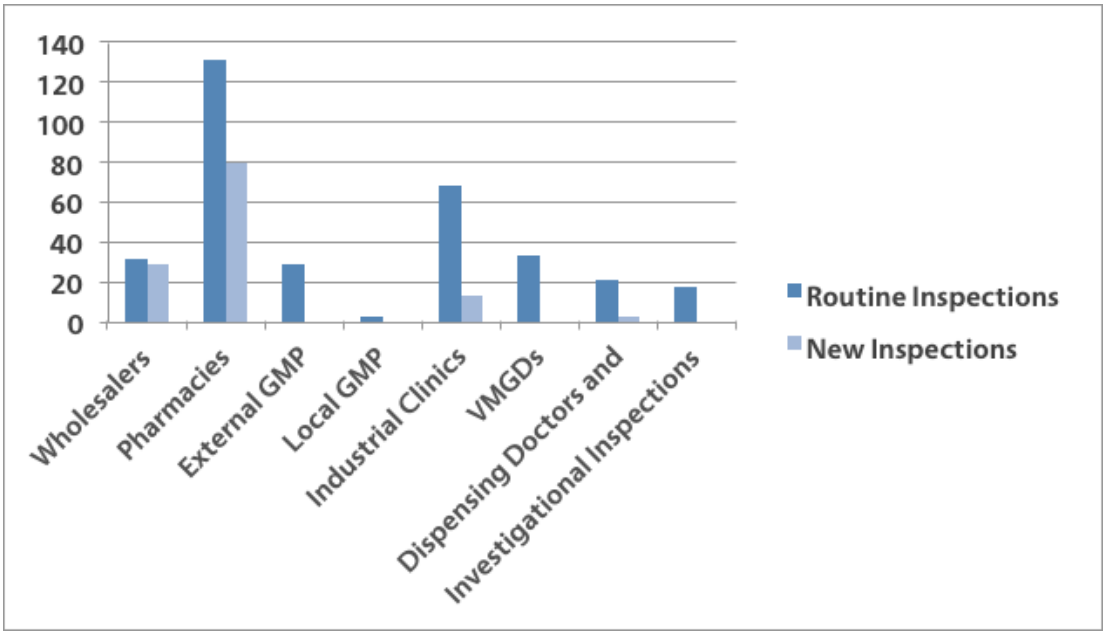


Figure 7: Number of new and routine inspections carried out in 2011 (Source: MCAZ Licensing and Enforcement December 2011)

INSPECTIONS BY INTERNATIONAL AUTHORITIES IN ZIMBABWE

MCAZ will, if requested, accompany inspections by foreign regulatory authorities of companies in Zimbabwe. The continued export of medicines by Zimbabwean manufacturers is based on their ability to maintain standards that are acceptable to the regulatory authorities where they export their medicines.

Activities

- •Foreign competent authorities carried out 4 GMP inspections of pharmaceutical companies in Zimbabwe. The inspections were performed by authorities from the Medicines Control Council of South Africa and the Ministry of Health of Botswana

Licensing and Advertising Committee

A panel of experts supports MCAZ in the assessment and provision of advice relating to the operation of premises and persons dealing in medicines.

Activities

- During the course of 2011 the Licensing and Advertising Committee held 11 scheduled meetings. The meetings are where the Licensing and Enforcement Unit reports on matters to do with inspections, advertising issues and also for the licensing and approval of new premises and persons.

Special Activities and Events in the Licensing and Enforcements

Strengthening of Import & Export Controls

- In order to strengthen the control of medicines through the ports of entry, MCAZ works in collaboration with ZIMRA and Port Health Officials. 68 ZIMRA & Port Health officers were trained using training material drafted for the purpose and supervisory visits to 7 ports of entry, namely Beitbridge, Forbes, Plumtree, J.M. Mqabuko Airport, Chirundu, Kariba and Nyamapanda were also conducted, with support from UNICEF.
- Harare International Airport continued to be monitored daily from Monday to Friday and all consignments containing medicines were physically verified.

Strengthening precursor substance control

2010 saw the slow implementation of the Medicines and Allied Substances Control (Import and Export of Precursor Substances) Regulations, 2008 (S.I. 58 of 2008).

- It was noted that limited awareness of the requirements for control of precursor substances largely contributed to the slow progress in 2010,
- 45 permits had been issued by end of 2011 after an advert was published in local newspapers.

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.

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.

Activities

- In 2011, MCAZ received and evaluated 200 reports of adverse reactions (ADRs), serious adverse events(SAEs), adverse following immunizations (AEFIs) associated with medicines and vaccines which had been submitted by approved clinical trials, medical professionals the pharmaceutical industry and Expanded Program on Immunization. Of these 200 safety reports, 56% are Adverse Drug Reactions and 44% are Adverse Events Following Immunisation (AEFIs).

- These reports led to the identification of new risks associated with medicine s and vaccines. Risk-minimising measures such as restrictions of indications, the inclusion of new warnings and precautions in the product information, and product recalls were adopted as appropriate. It was noted that for serious adverse events, the appropriate clinical management was effectively done and most patients recovered.

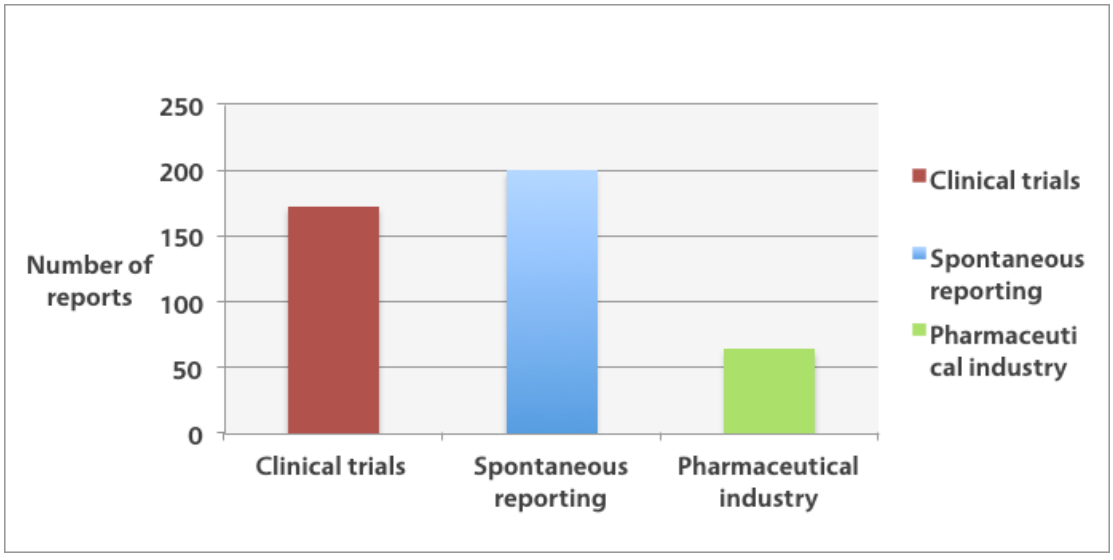


Figure 8:Adverse Events and Serious Adverse Events reported in 2011 (Source: MCAZ Pharmacovigilance and Clinical Trials, December 2011)

CLINICAL TRIALS ON MEDICINAL PRODUCTS

Clinical trials of medicines, vaccines and medical devices are used for the systematic gathering of information on medicinal products used on persons. MCAZ has a mandate to monitor clinical trials of medicines, vaccines and medical devices including subject protection, and technical scientific information. No Clinical trials of medicines may be conducted in Zimbabwe without prior written approval from the MCAZ, which is granted by the Secretary for Health and Child Welfare. Ethical approval should also be obtained from the Medical Research Council of Zimbabwe (MRCZ).

Activities

- MCAZ received 5 new clinical trials applications in 2011 that were evaluated and approved.15 clinical trial amendments and 6 Data Safety Monitoring Board reports were considered and approved.

- The collaboration between MCAZ and the Medical Research Council of Zimbabwe (MRCZ) was continued in 2011 including joint GCP inspections.

- In 2011, the staff of the Pharmacovigilance and Clinical Trial attended various international and local training courses, for instance Good Clinical Practice (GCP).

- 6 GCP inspections were carried out in 2011 for approved clinical trials.

POST-REGISTRATION AMENDMENTS

MCAZ approves amendments including variations to registered medicines such as change of packaging, trade name etc. MCAZ receives applications for approval of amendments to registered medicines including re-instatement of registration of a cancelled product as per the guidelines.

Activities

- In 2011, 150 amendments to registered medicines were submitted and 141 were evaluated and approved. The timeline for approval was 3-4 months.

- Some amendments received in 2010 were still ongoing owing to the submission of inadequate information by applicants and final reminders were sent.

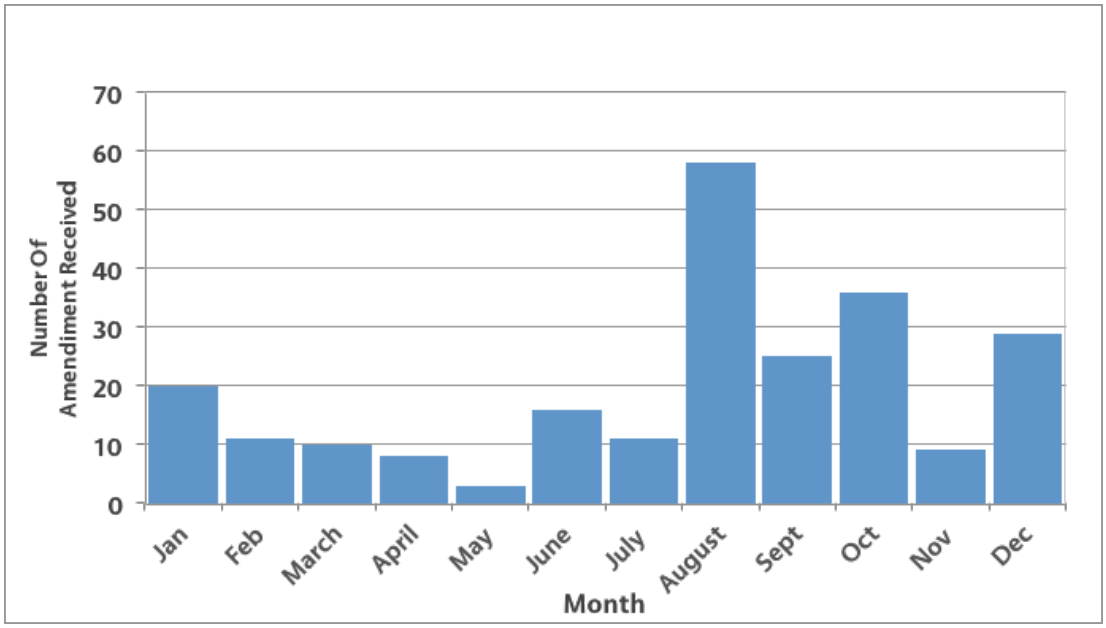


Figure 9: Amendments to Registered Medicines received in 2011 (Source: MCAZ Pharmacovigilance and Clinical Trials, December 2011)

PRODUCT RETENTION ON THE REGISTER

A human and veterinary medicinal product is registered and retained on the registered medicinal products register every year after payment of an annual retention fee. The applicant must pay annual retention fee for the products registration to be maintained. Voluntary withdrawal of registration or cancellation must be officially reported to the MCAZ by the applicant.

Activities

- In 2011, 98% foreign human medicinal products, 95% local human medicinal products, 90% foreign veterinary medicinal products and 70% local veterinary medicinal products were retained on the market

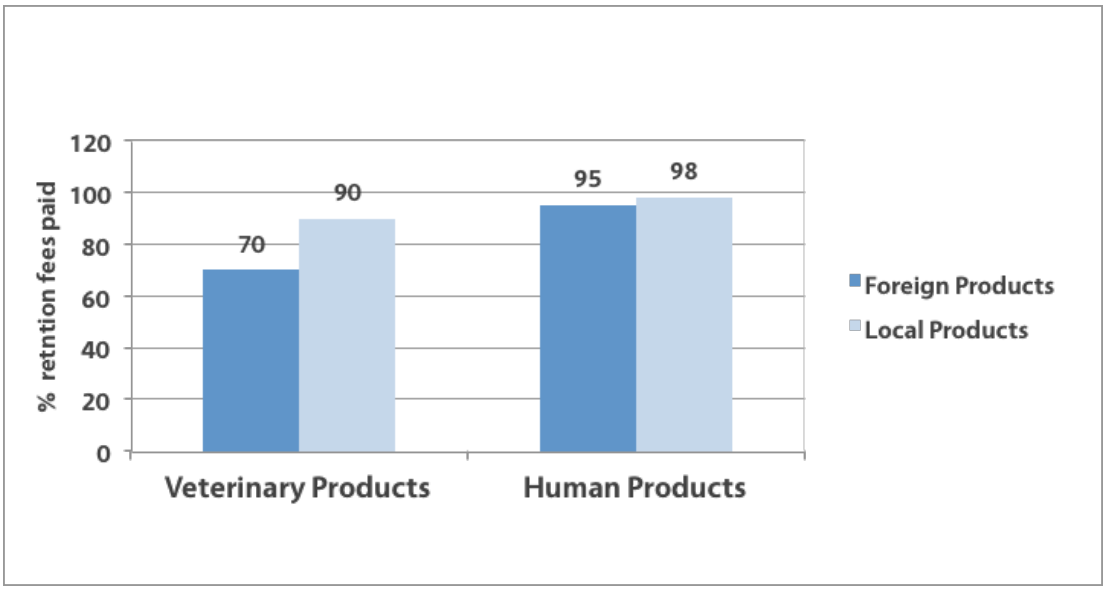


Figure 10: Retention fee payment for medicinal products in 2011 (Source: MCAZ Pharmacovigilance and Clinical Trials, December 2011)

Pharmacovigilance and Clinical Trials Committee

A panel of experts supports MCAZ in assessment and provision of advice relating to the adverse drug reactions, adverse events following immunisation, and clinical trials.

Activities

- During the course of 2011 the Committee panel held 11 meetings to issue recommendations on pharmacovigilance and clinical trials. These related in particular to evaluation of scientific information on clinical trials and safety reports

Special Activities and Events in the Pharmacovigilance and Clinical Trials

Strengthening National Surveillance of Adverse Events Following Immunisation

The World Health Organisation (WHO/HQ/FWC/IVB/NRA and GVS) team in collaboration with the MCAZ organised a national training workshop on Strengthening Surveillance of AEFIs in Harare at the Holiday Inn Hotel from the 26th to 29th of April 2011. The workshop was designed for regulatory authority staff and staff from the national immunisation programme as a training of trainers (TOT). The workshop focused on establishing a safety surveillance programme for adverse events following immunisation and how to communicate with the public. Participants from MCAZ and from the Ministry of Health EPI and from the WHO country office EPI and UNICEF EPI attended the workshop. The training workshop was funded by WHO/HQ. Following the successful hosting of this training, MCAZ and EPI trainers trained 160 staff from 6 provinces from the private and public sectors.

Safety Monitoring of H1N1 Vaccine (August 2010 to August 2011)

The MCAZ through the PVCT Unit conducted the safety monitoring of the H1N1 vaccine from August 2010 to 2011, in collaboration with The MoHCW Expanded Programme on Immunization (EPI) in all the 10 provinces countrywide. The MCAZ acknowledges with thanks all the support and reports received from all provinces, EPI and WHO. 51 Adverse Events Following Immunization (AEFI) reports were associated with H1N1 vaccine from the 500 000 + participants vaccinated i.e. less than 0.01% AEFIs. The AEFI reports were entered in Paniflow databases. The Unit will finalise the data analysis including publication, and hold a feedback stakeholders meeting before end of 2012. The common AEFI reactions due to the H1N1 vaccination were headache, fever, vomiting, weakness and rash.

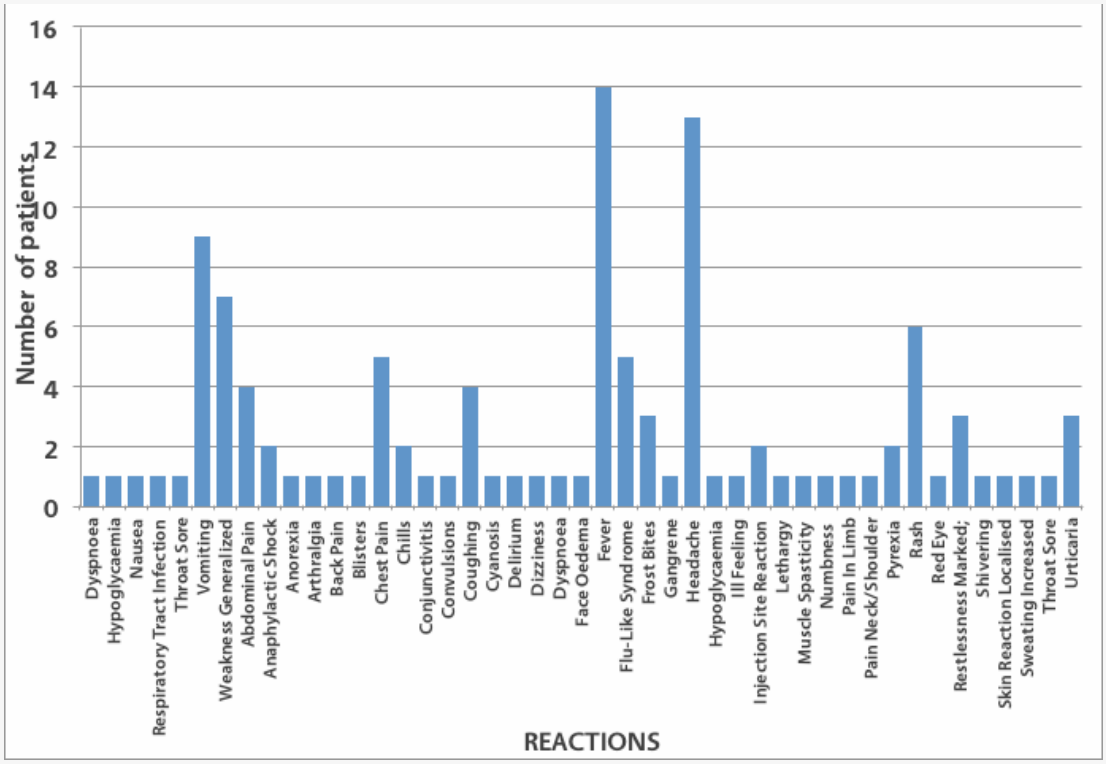


Figure 11: Summary of H1N1 pandemic influenza vaccine AEFI reactions (Source: MCAZ Pharmacovigilance and Clinical Trials, December 2011)

Targeted Spontaneous Reporting (TSR) of Antimalarial Medicines

The PVCT Unit introduced a new active pharmacovigilance programme known as targeted spontaneous reporting (TSR) for all antimalarial medicines in September 2011 in all the provinces that had previously conducted the Cohort Event Monitoring (CEM) of Artemisinin Combination Therapy (ACTs) programme. A total of 240 Healthcare professionals were trained from the 5 provinces and ADR reporting forms distributed. Feedback on the outcome of the CEM of ACTs was given and any pending forms collected. The program was conducted in collaboration with the MoHCW National Malaria Control Programme and funded with the Global Fund. Two PVCT Unit regulatory officers were trained by the WHO in Nairobi Kenya in June 2011 on how to conduct the TSR programme. Data collection is still on going and results will be published in 2013.

The ISO/IEC 17025 accredited MCAZ laboratory is responsible for laboratory analysis and assessments of medicinal products and medical devices.

CHEMISTRY

Activities

- At the end of 2011, 239 sample products had been received for analysis, 204 were analysed and 20 had analysis cancelled due to the unavailability of standards.
- The laboratory managed to maintain its ISO/IEC 17025 accreditation for the HPLC technique following another successful visit by auditors from the South African National Accreditation Scheme (SANAS).
- With support from UNICEF there was a marked increase in the number of samples for post marketing surveillance.

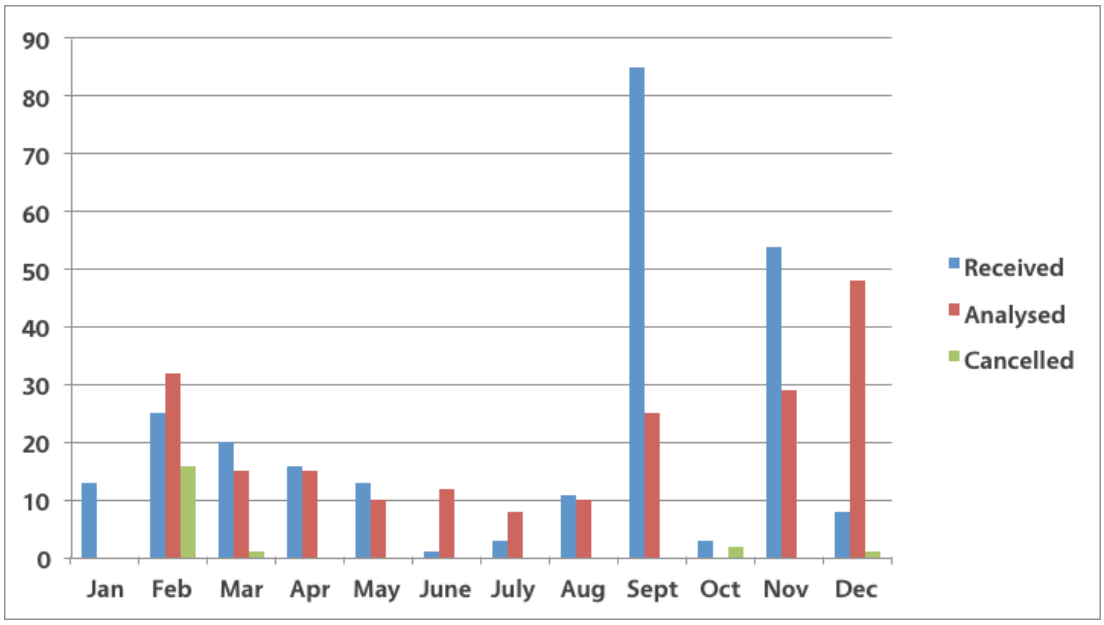


Figure 12: Summary of sample products in the Chemistry Laboratory in 2011 (Source: MCAZ Chemistry Laboratory, December 2011)

Laboratory Services
(continued)

MICROBIOLOGY

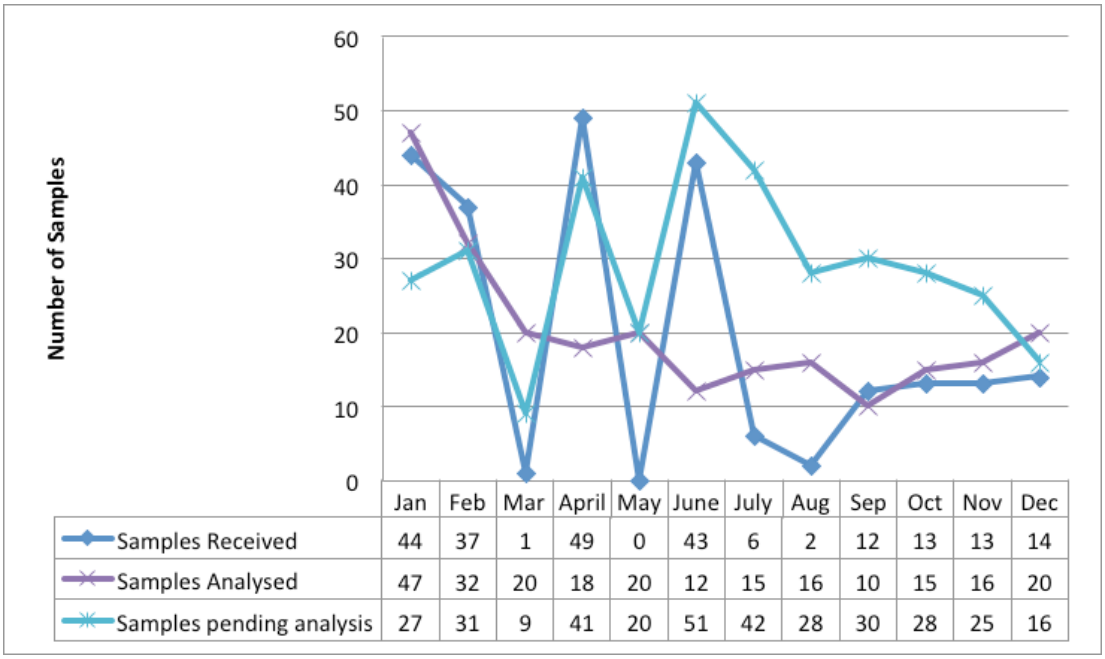
The Microbiology Laboratory examines products under the purview of the Medicines and Allied Substances Control Act for pathogenic and non-pathogenic microorganisms, review of microbiology data and assessing medicinal products for potency and assessing biopharmaceuticals including lot release.

Activities

- In 2011, 234 sample products were received for analysis. This is an increase of 47 samples from the previous years.
- 221 samples were analysed and 16 were pending analysis at the end of the year.
- Complementary medicines represented 65% of the samples brought for analysis.
- 5 summary protocols were received for lot release from EPI and 1 was for product registration.
- Reviews for vaccine product files, cGMP reports and clinical trial applications for vaccines was part of the activities routinely carried out

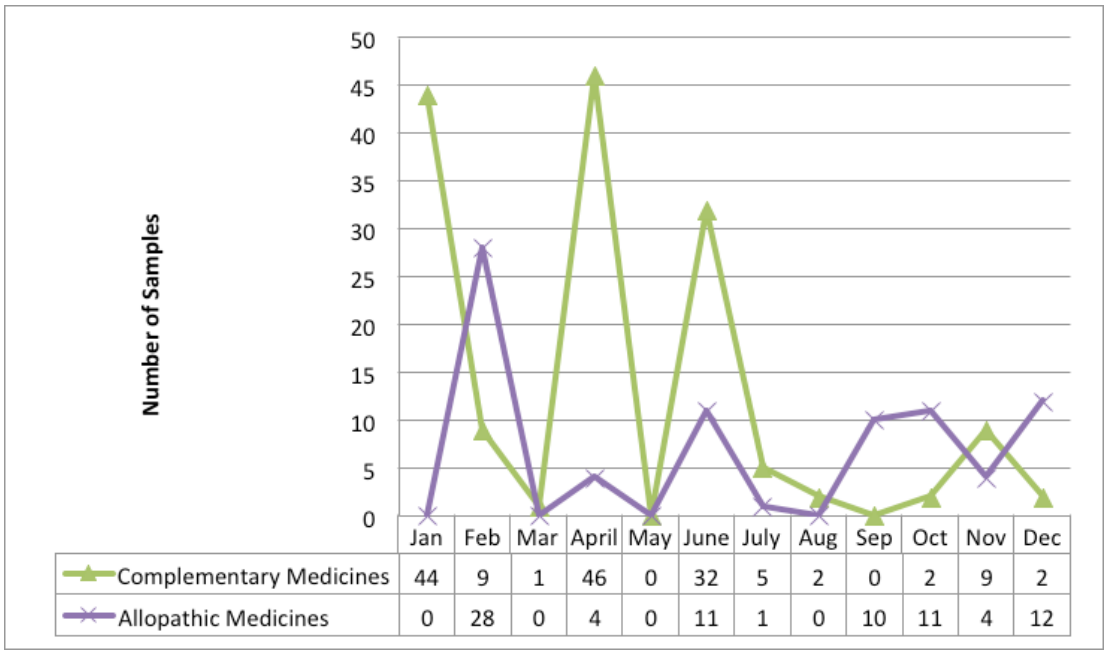
Table 1: Number of sample products received in the Microbiology Laboratory (Source: MCAZ Microbiology, December 2011)

Year	Number of Samples
2006	30
2007	58
2008	63
2009	70
2010	187
2011	234



	Jan	Feb	Mar	April	May	June	July	Aug	Sep	Oct	Nov	Dec
Samples Received	44	37	1	49	0	43	6	2	12	13	13	14
Samples Analysed	47	32	20	18	20	12	15	16	10	15	16	20
Samples pending analysis	27	31	9	41	20	51	42	28	30	28	25	16

Figure 13: Summary of product samples received, analysed and pending analysis monthly in 2011 (Source: MCAZ Microbiology, December 2011)



	Jan	Feb	Mar	April	May	June	July	Aug	Sep	Oct	Nov	Dec
Complementary Medicines	44	9	1	46	0	32	5	2	0	2	9	2
Allopathic Medicines	0	28	0	4	0	11	1	0	10	11	4	12

Figure 14: Breakdown of types of product samples monthly in 2011 (Source: MCAZ Microbiology, December 2011)

Laboratory Services
(continued)

Medical Devices

Activities

- In 2011, 264 batches of condoms were received, 339 were tested (This included batches from 2010).
- 56 batches of gloves were received for analysis in 2011, and all 56 were analysed.
- The laboratory managed to maintain its ISO/IEC 17025 accreditation following another visit by auditors from the South African National Accreditation Scheme (SANAS).
- The laboratory also continued to participate in its annual proficiency testing schemes with Family Health International (FHI), USA and Enersol, Australia

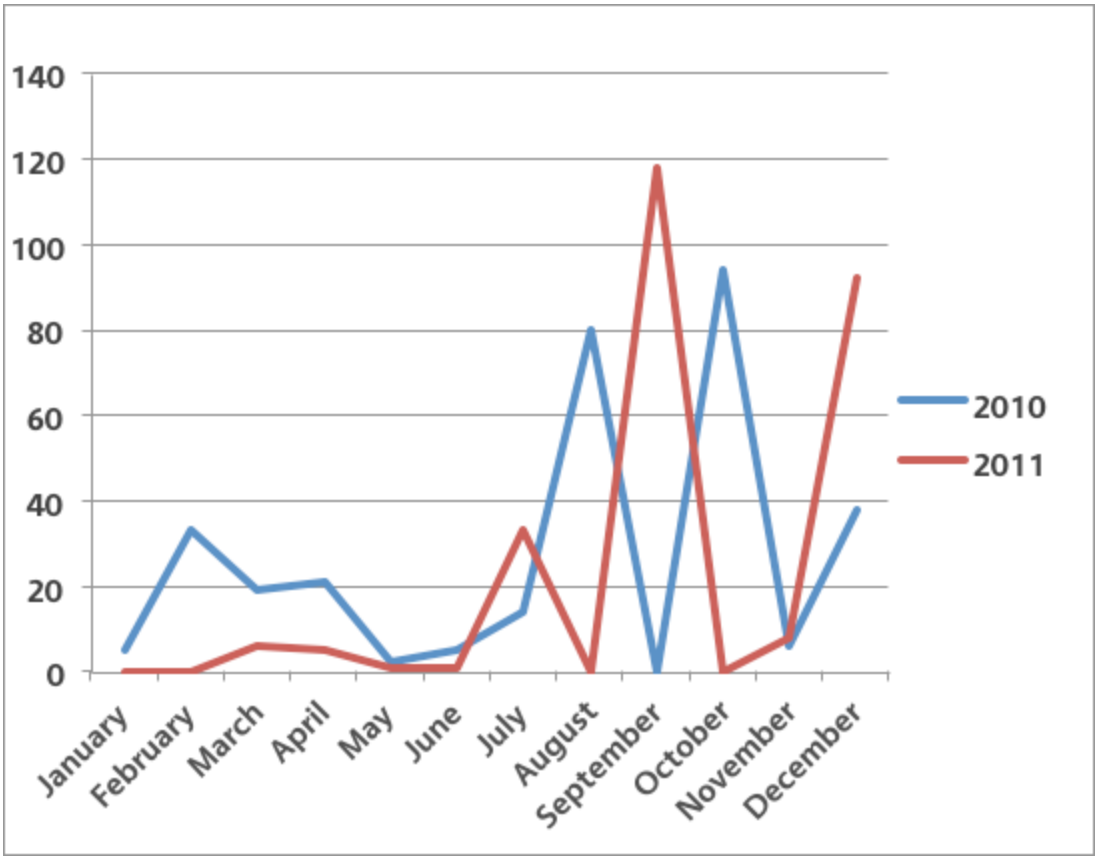


Figure 15: Summary of condom samples received in 2010 and 2011 (Source: MCAZ Microbiology, December 2011)

Laboratory Committee

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

Activities

- During the course of its 6 meetings, the Laboratory Committee issued recommendations on product samples that were analysed in the 3 laboratories.

- MCAZ has developed terms of reference for the Laboratory Committee on behalf of the Authority. The TOR was adapted from WHO guidelines and the Corporate Governance Framework for State Enterprises and Parastatals.

Special Activities and Events in the Laboratory Services

MCAZ organised training for local pharmaceutical industry

The laboratories managed to host participants drawn from the local pharmaceutical manufacturing companies to carry out 1 week long workshops in analytical techniques at the MCAZ laboratories. This training was targeted for analysts from the local industry to improve on their competencies. This training was carried out in the Chemistry and Microbiology Laboratories.

Laboratories received support from UNDP Global Fund Round 8

MCAZ as the country's regulatory authority received a line budget from the Global Fund for quality testing of medicines. This support was targeted to support the laboratory to purchase equipment that would be used in the analysis of medicines. The value of the support was US$ 444, 821,00.

Post-marketing Surveillance of Medicines and Medical Devices

Surveillance inspections were carried out in partnership with the Licensing and Enforcement teams to ensure condoms and gloves used throughout the country were being approved for the distribution by MCAZ and were being stored properly. The surveillance inspections would also check if condoms and gloves on the market were still within their shelf life. With support from UNICEF, MCAZ also managed to carry out a PMS program for essential medicines that were being used in the public sector to check for good distribution practices and good storage practices.





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