

# **OFFICE OF THE AUDITOR GENERAL**

Performance Audit Report on the Control and Regulation of Medicines in Zambia: 2019 - 2022





Republic of Zambia

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## **FOREWORD**

I have the honour to publish and submit the Performance Audit Report on the Control and Regulation of Medicines in Zambia. In accordance with the Provisions of Article 250 of the Constitution of Zambia (Amendment) Act No. 2 of 2016, Public Audit Act No.13 of 1980 and the Public Finance Management Act No. 1 of 2018, I am mandated to carry out Performance Audits in Ministries, Provinces and Agencies (MPAs).

The importance of quality medicines is identified as a global need with the Sustainable Development Goal (SDG) No.3 "Good Health and Well-being" specifically Target 3.8 requiring all United Nations member states to achieve universal health coverage, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all by 2030. The control and regulation of medicines is directly linked to the Eighth National Development Plan (8NDP) through Strategic Development Area 2: Human and Social Development, Development Outcome 2 which aims to improve health, food and nutrition. As Zambia strives to achieve the Agenda 2030, my Office will continue to contribute towards this achievement by auditing the implementation of the SDGs.

I therefore, present to you this Performance Audit Report together with recommendations, which if implemented by Ministry of Health through Zambia Medicines Regulatory Authority will ensure that measures put in place by the Authority are efficient and effective in protecting and enhancing public health through the control and regulation of medicines in the country.

I wish to take this opportunity to thank the management and staff of Zambia Medicines Regulatory Authority for the cooperation and assistance rendered during the audit.

Dr. Dick Chellah Sichembe

**AUDITOR GENERAL** 

## TABLE OF CONTENTS

FOREWORD	i
TABLE OF CONTENTS	ii
LIST OF FIGURES	iii
LIST OF TABLES	iv
LIST OF APPENDICES	v
GLOSSARY OF TERMS	vi
ACRONYMS	X
EXECUTIVE SUMMARY	xii
CHAPTER 1: INTRODUCTION	1
CHAPTER 2: AUDIT OBJECTIVE AND AUDIT QUESTIONS	6
CHAPTER 3: METHODOLOGY	8
CHAPTER 4: DESCRIPTION OF THE AUDIT AREA	10
CHAPTER 5: AUDIT CRITERIA	16
CHAPTER 6: FINDINGS	20
CHAPTER 7: CONCLUSIONS	53
CHAPTER 8: RECOMMENDATIONS	55
APPENDICES	56

## **LIST OF FIGURES**

Figure 1.1: The Three Pillars of Medicines Regulation	3
Figure 4.1 - ZAMRA Organogram	11
Figure 6.1: Statistics of Number of Marketing Authorisations received by the Authority	20
Figure 6.2: Marketing AuthorisationApplications Evaluated and Granted	21
Figure 6.3: Import Permits Processed from 2019 - 2021	23
Figure 6.4: Seized Unauthorised Products at Fresh View Pharmacy in Mongu	25
Figure 6.5: Seized Care Solution at AB Pharmacy in Ndola	25
Figure 6.6: Prosecuted retail pharmacies and health shops 2019 – June 2022	28
Figure 6.7: Trend of GMP Inspections from 2017 - 2021	31
Figure 6.8: Stained ceiling due to leakages at Five Star Pharmacy in Lusaka	35
Figure 6.9: Vaccines mixed with food and drinks at Lusaka Health Care Pharmacy in Lusaka	35
Figure 6.10: Medicines Comingled with Allied Substances at Nimoz Pharmacy in Lusaka	36
Figure 6.11: Planned versus Samples Collected 2019 - May 2022	40

## **LIST OF TABLES**

Table 4.1: Funding Arrangements	13
Table 6.1: Unauthorised Medicines	22
Table 6.2: Number of New Registrations 2019 - 2022	26
Table 6.3: Number of Post Licensing Inspections	32
Table 6.4: Registered premises that have not had post licensing inspections	33
Table 6.5: Coverage, available staff and number of premises per region	34
Table 6.6: Sampling Plans 2019 - 2022	39
Table 6.7: Pharmacovigilance reports received and processed	42
Table 6.8: Samples Received vs Processed 2019- June 2022	44
Table 6.9: Lead Time for Sample Analysis 2019 to October 2022	45
Figure 6.12: Trend of percentage of samples tested within 21 days in 2019 - 2022	45
Table 6.10: Public Relations Section Budget vs Funding for Sensitisation Activities 2019 to 2022	49
Figure 6.13: Level of Awareness of ZAMRAs Mandate	50

## LIST OF APPENDICES

Appendix 1: List of Sampled Premises	56
Appendix 2a: List of interviewees – ZAMRA	61
Appendix 2b: List of interviewees - Key Stakeholders	62
Appendix 2c: List of interviewees – Local Authorities	62
Appendix 2d: List of interviewees – Regulated premises	63
Appendix 3: List of Documents Reviewed	68
Appendix 4: Court cases on importation of medicines without an import permit	69
Appendix 5: List of registered wholesale pharmacies and drug manufacturing companies	70
Appendix 6: List of Local Authorities that submitted information	72
Appendix 7: List of registered and unregistered premises with Local Authorities and ZAMRA	73
Appendix 8: Public and Private Hospital Pharmacies Inspected	93
Appendix 9: Physical Inspection Findings on Unregistered Premises	95
Appendix 10: List of Physically Inspected Registered Premises that have had a Post Licensing Inspection	98
Appendix 11: ZAMRAs Presence in Regions in Comparison with Geographical Location and Man Power.	102
Appendix 12: Field Inspection Findings on Registered Premises	105
Appendix 13: Seizure forms for products sold in unregistered outlets	111
Appendix 14: Level of adherence to the Authroritys recommendations	122
Appendix 15: Target Vs Product Sampled 2019 to May 2022	128
Appendix 16: List of medicines recalled 2019 - 2022	130
Appendix 17: Qualification and Maintenance of Laboratory Equipment 2019 to 2022	133
Appendix 18: Planned vs Actual Sensitisation	143
Appendix 19: Sensitisation activities undertaken 2019- September 2022	144

## **GLOSSARY OF TERMS**

Authority	The Zambia Medicines Regulatory Authority. <sup>1</sup>	
ASCYUDA WORLD	A computerised customs management system that covers most foreign trade procedures. It handles manifests and customs declarations, along with accounting, transit and suspense procedures. It also generates trade data that can be used for statistical economic analysis. <sup>2</sup>	
Calibration	A set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. <sup>3</sup>	
Certificate of	Refers to test results from any approved laboratory that verify the quality,	
Analysis	efficacy and safety of medicines. <sup>4</sup>	
Certificate of registration	Means the certificate of registration of a pharmacy. <sup>5</sup>	
Cross- contamination	Contamination of a starting material, intermediate product or finished medicines and allied substance with another starting material or product during production, storage and transportation. <sup>6</sup>	
Counterfeit medicine	Medicine which is deliberately or fraudulently mislabeled or misrepresented with respect to identity or source, or a medicine or allied substance which—  (a) has wrong ingredients; (b) contains active ingredients or not; (c) has insufficient or excess active ingredients; or (d) has fake packaging. <sup>7</sup>	
Destination inspections	Destination inspections or sometimes known as pre-approval inspections are considered to be an important part of the application review and approval process. They represent a considerable workload, inspections are	

<sup>&</sup>lt;sup>1</sup>MASA No. 3 of 2013, Part I, Section (2)

<sup>&</sup>lt;sup>2</sup>https://asycuda.org/en/about/

<sup>3</sup> WHO GPPQCL Annex 1 Glossary

<sup>4</sup> MASA No.3 of 2013, Part VII Section 54 (7)

<sup>&</sup>lt;sup>5</sup> MASA No. 3 of 2013 Part 1 section 2

<sup>&</sup>lt;sup>6</sup> WHO Guidelines for Good Manufacturing Practices

<sup>&</sup>lt;sup>7</sup>MASA No.3 off 2013 part 1 section 2

	not normally carried out routinely, but rather only in specific cases where				
	non-compliance is possible. <sup>8</sup>				
Distribution	The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of medicines and allied substances, with the exception of the dispensing or providing medicines and allied substances directly to a patient or his or her agent. <sup>9</sup>				
Efficacy	Refers to the ability and amount of a drug that's necessary to produce a desired effect. <sup>10</sup>				
Fake drugs	Drugs which generally contain wrong doses, incorrect ingredients or no active ingredients at all. <sup>11</sup>				
Good	A part of quality assurance which ensures that pharmaceutical products are				
Manufacturing	consistently produced and controlled to quality standards appropriate to				
Practices (GMP)	their intended use and as required by marketing authorisation. <sup>12</sup>				
Health facility	Any site, fixed or mobile, providing services for the prevention, diagnosis and treatment of disease or illness and includes a diagnostic centre, a hospice and a hospital. <sup>13</sup>				
Health shop	A place or premises permitted to sell a prescribed list of medicine by the Authority, under the control of an authorised person as determined by the Authority <sup>14</sup>				
Hospital	A health institution providing in-patient health care under the supervision of a medical doctor, which includes one or more of the following health services: medicine; surgery; obstetrics and gynaecology; or paediatrics. <sup>15</sup>				
Hospital pharmacy	A pharmacy which is part of a health facility. 16				
Inspector's Book	This is a mandatory document to be kept by all registered pharmaceutical business premises for purposes of inspectors recording deficiencies found during the time of inspection of regulated premises as well as proposed preventative and corrective actions including timelines. It is signed off by				

<sup>-</sup>

<sup>&</sup>lt;sup>8</sup> WHO Quality assurance of pharmaceuticals Compendum Guidelines 2nd Edition

<sup>&</sup>lt;sup>9</sup> WHO Guidelines for Good Manufacturing Practices

<sup>&</sup>lt;sup>10</sup> Tripathi, K. D. (2013). Essentials of medical pharmacology (7th edition). New Delhi: Jaypee Brothers Medical Publishers.

<sup>11&</sup>lt;a href="https://medical-dictionary.thefreedictionary.com/Fake+drugs">counterfeit drug</a>

<sup>&</sup>lt;sup>12</sup> WHO GPPQCL Annex 1 Glossary of terms

<sup>&</sup>lt;sup>13</sup> Health Professions Act. No. 24 of 2009

<sup>&</sup>lt;sup>14</sup>MASA No.3 of 2013 part I section 2

<sup>&</sup>lt;sup>15</sup> Health Professions Act. No. 24 of 2009

<sup>&</sup>lt;sup>16</sup>MASA No.3 of 2013 part I section 2

	the lead inspector of ZAMRA and the responsible pharmacist of the				
	pharmaceutical outlet. <sup>17</sup>				
	pnarmaceutical outlet.				
Market	The authorisation granted for the placement of a medicine on the market. 18				
Authorisation					
	Human medicine, medicinal product, herbal medicine or any substance or				
	mixture of substances for human use intended to be used or manufactured				
Medicine	for use for its therapeutic efficacy or for its pharmacological purpose in the				
	diagnosis, treatment, alleviation, modification or prevention of disease or				
	abnormal physical or mental state or the symptoms of disease in a person. <sup>19</sup>				
D + M 1 +	The practice of monitoring the safety of a drug or medical device after it has				
Post-Marketing	been released on the market and is an important part of the science of				
Surveillance	pharmacovigilance. <sup>20</sup>				
Pharmaceutical	A license issued by ZAMRA to manufacture, distribute or deal in a				
License	medicine or allied substance. <sup>21</sup>				
	The science and activities relating to the detection, assessment,				
Pharmacovigilance	understanding and prevention of adverse effects or any other drug-related				
C	problem. <sup>22</sup>				
Pharmacist	A person trained in pharmacy and licensed to practice. <sup>23</sup>				
	A drugstore, druggist, chemist or any business or premises registered as				
Pharmacy	such under section sixteen of the MASA. <sup>24</sup>				
Prescription only	25				
medicine	Medicine dispensed only on prescription. <sup>23</sup>				
DI .	A book containing an official list of medicinal drugs together with articles				
Pharmacopoeia	on their preparation and use. <sup>26</sup>				
	A process for withdrawing or removing medicines and allied substances				
Product recall	from the pharmaceutical distribution chain because of defects in the				
	product, complaints of serious adverse reactions to the product or concerns				
medicine Pharmacopoeia	A process for withdrawing or removing medicines and allied substances from the pharmaceutical distribution chain because of defects in the				

<sup>&</sup>lt;sup>17</sup> ZAMRA Guidelines on the establishment of Pharmaceutical Wholesale Outlet, Retail outlet and Health Shop.

<sup>&</sup>lt;sup>18</sup>MASA No.3 of 2013 part I section 2 <sup>19</sup>MASA No.3 of 2013 part I section 2

<sup>&</sup>lt;sup>20</sup>Interviews with ZAMRA

<sup>&</sup>lt;sup>21</sup>MASA No. 3 2013 Part I Section 2(d)

AU Model Law on Medicines and Medical devices - 2016
 https://medical-dictionary.thefreedictionary.com/pharmacist

<sup>&</sup>lt;sup>24</sup>MASA No. 3 2013 Part I Section 2

<sup>&</sup>lt;sup>25</sup>MASA No. 3 2013 Part I Section 2

 $<sup>^{26}</sup> https://medical\text{-}dictionary.the free dictionary.com/Pharmacopoeia$ 

	that the product is or may be counterfeit. The recall might be initiated by the				
	manufacturer, importer, wholesaler, distributor or a responsible agency. <sup>27</sup>				
Qualification	Action of proving that any premises, systems and items of equipment work				
Quantication	correctly and actually lead to the expected results. <sup>28</sup>				
	Substance or compound that is added to a system in order to bring about a				
Reagent	chemical reaction or is added to see if a reaction occurs. Such a reaction is				
	used to confirm the presence of another substance. <sup>29</sup>				
	Material sufficiently homogeneous and stable with respect to one or more				
Reference Material	specified properties, which has been established to be fit for its intended use				
	in a measurement process. <sup>30</sup>				
Regulated	These are Wholesale, Retail, Hospital and Health shops issued with a				
premises	pharmaceutical license. <sup>31</sup>				
Danulataur	A formal process based on specified policies, principles and associated				
Regulatory Processes	criteria and follows specified procedures as established in the management				
Processes	system. <sup>32</sup>				
Regulatory	The combination of institutions, processes and the regulatory framework				
Systems	with which a government controls particular aspects of an activity. <sup>33</sup>				
	Operations designed to obtain a representative portion of a medicine and				
Campling	allied substances, based on an appropriate statistical procedure, for a				
Sampling	defined purpose, for example acceptance of consignments or batch				
	release. <sup>34</sup>				
The National	The institution in charge of assuring the quality, safety, and efficacy of				
Regulatory	medical products as well as ensuring the relevance and accuracy of product				
Authority	information. <sup>35</sup>				
Unregistered or	Products that have not undergone evaluation or approval by a National				
Unlicensed	Medicines Regulatory Authority for the market in which they are marketed				
Medical Products	or distributed. <sup>36</sup>				
ZAMRA	Mandatory book to be kept by a registered pharmaceutical business used to				
Inspectors' book	record findings by an inspector during their inspections. <sup>37</sup>				

<sup>&</sup>lt;sup>27</sup> ZAMRA Good Distribution Practices Guidelines

<sup>&</sup>lt;sup>28</sup> Annex 2 WHO good manufacturing practices for pharmaceutical products: main principles1

<sup>&</sup>lt;sup>29</sup>www.reagent.co.uk

<sup>&</sup>lt;sup>30</sup> WHO GPPQCL Annex 1 Glossary

<sup>&</sup>lt;sup>31</sup>Interviews with ZAMRA

<sup>&</sup>lt;sup>32</sup>Regulatory Process - an overview | ScienceDirect Topics

<sup>&</sup>lt;sup>33</sup>Annex 11 Good Regulatory Practices in the Regulation of Medical Product WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-fifth report

<sup>&</sup>lt;sup>34</sup> ZAMRA Good Distribution Practices Guidelines

<sup>&</sup>lt;sup>35</sup>WHO Global Benchmarking Tool Plus (Gbt+) For Evaluation Of National Regulatory System Of Medical Products National Regulatory System (Rs): Indicators and Fact Sheets Revision Vi+ Version 1 November 2019 <sup>36</sup>Interviews with ZAMRA

<sup>&</sup>lt;sup>37</sup> ZAMRA guidelines for establishing Pharmaceutical retail Business

## **ACRONYMS**

7NDP	Seventh National Development Plan			
8NDP	Eighth National Development Plan			
ASCYUDA	Automated System for Customs Data			
AU	African Union			
ADB	Asian Development Bank			
ADE	Adverse Drug Events			
ADR	Adverse Drug Reactions			
ART	Antiretroviral Therapy			
CEO	Chief Executive Officer			
CPs	Cooperating Partners			
CTD	Common Technical Document			
DG	Director General			
DDA	Dangerous Drug Act			
DEC	Drug Enforcement Commission			
DMC	Director Medicines Control			
FIFO	First In First Out			
GDP	Good Distribution Practices			
GMP	Good Manufacturing Practices			
HPCZ	Health Professionals Council of Zambia			
IEC	Information, Education and Communication			
ISSAI	International Standards of Supreme Audit Institutions			
ISO	International Organisation for Standardisation			
INTOSAI	International Organisation for Supreme Audit Institutions			
KKIA	Kenneth Kaunda International Airport			

MA	Market Authorisation			
MASA	Medicines and Allied Substances Act			
MDG	Millennium Development Goal			
МОН	Ministry of Health			
MOU	Memorandum of Understanding			
MTEF	Medium Term Expenditure Framework			
NDQCL	National Drug Quality Control Laboratory			
NMRAs	National Medicines Regulatory Authorities			
NPVU	National Pharmacovigilance Unit			
OTC	Over the Counter			
POMs	Prescription Only Medicines			
PMS	Post Market Surveillance			
PRO	Principal Regulatory Officer			
PSO	Principal Surveillance Officer			
SDG	Sustainable Development Goal			
SO	Surveillance Officer			
SOPs	Standard Operating Procedures			
SSFFCs	Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit Medical Products			
TWG	Technical Working Group			
WHO	World Health Organisation			
WHOGPPQCL	World Health Organisation Good Practices for Pharmaceutical Quality Control Laboratory			
ZAMMSA	Zambia Medicines and Medical Supplies Agency			
ZAMRA	Zambia Medicines Regulatory Authority			
ZAZIBONA	Zambia Zimbabwe Botswana Namibia			
ZDA	Zambia Development Agency			
ZRA	Zambia Revenue Authority			

## **EXECUTIVE SUMMARY**

Medicines are essential to health care and should be available to all citizens. Medicines are safely used every day to treat diseases, however, there have been adverse events over the years to prove that consumption of medicines also carries risks. Zambia Medicines Regulatory Authority (ZAMRA), a statutory body under the Ministry of Health (MoH) is responsible for medicines regulation in Zambia.

The pharmaceutical industry not only in the country but world wide has had challenges with counterfeit products, and the sale and distribution of medicines illegally. It is thus imperative for Government to protect and promote the health and safety of the public through a well-functioning health care system that ensures that medicines are safe, efficacious and of assured quality.

The objective of the audit was to assess whether measures put in place by Zambia Medicines Regulatory Authority (ZAMRA) are efficient and effective in protecting and enhancing public health through the control and regulation of medicines. The audit covered the period 2019 to 2022.

The audit methodology included document review, interviews with key stakeholders, observation and physical inspections.

Criteria used was obtained from the following sources: The Medicines and Allied Substances Act No. 3 of 2013; National Health Policy 2012; ZAMRA Public Relations Policy 2021; ZAMRA Strategic Plan 2019 – 2021; ZAMRA Pharmacovigilance Reference Manual Second Edition March 2020; ZAMRA Annual Work Plans 2019 to 2021; ZAMRA Standards of Pharmaceutical Practice; ZAMRA Service Charter; International Organisation of Standardisation (ISO) 17025; and World Health Organisation Good Practices for Pharmaceutical Quality Control Laboratory (WHOGPPQCL).

The audit established that not all marketing authorisation applications received during the period under review were evaluated, there were weaknesses in monitoring the importation of medicines and unauthorised products were sold on the Zambian market. The audit also established that some retail pharmacies and health shops operated without a certificate of registration and health shop permit respectively. The Authority's enforcement was also not robust enough to deter noncompliance with the Medicines and Allied Substance Act No. 3 of 2013.

Furthermore, the audit established that the National Drug Quality Control Laboratory (NDQCL) was not ISO 17025 accredited as the Authority had not satisfied the necessary requirements. In addition, there was low sensitisation coverage to the public and that while ZAMRA had some collaboration with various stakeholders, the collaboration was not strong enough to enhance enforcement and regulation of medicines in the country.

The audit concluded that ZAMRA had measures in place to control and regulate medicines, however, implementation was not supported by enhanced enforcement that would guarantee protection,safety and enhancement of public health.

The recommendations included that the Authority should: consider strengthening and building capacity; develop punitive measures for pharmacy outlets that fail to implement the recommendations; consider strengthening enforcement tools; ensure non-operation of erring pharmaceutical outlets; and strive to meet the conditions necessary for the ISO accreditation of its laboratory.

## **CHAPTER 1: INTRODUCTION**

#### 1.0 Introduction

This chapter highlights the mandate of the Office of the Auditor General (OAG), the background and motivation of the audit and the expected benefit to society. The title of the audit is "The Control and Regulation of Medicines in Zambia".

#### 1.1 Mandate

In accordance with the provisions of Article 250 of the Constitution of Zambia (Amendment) Act No.2 of 2016, Public Audit Act No.13 of 1994 and Public Finance Management Act No.1 of 2018, the OAG is mandated to carry out performance audits in Ministries, Provinces and Agencies (MPAs) and to report the results to the President and Parliament for debate. With this mandate, the OAG conducted a performance audit for purposes of assessing whether measures put in place by Zambia Medicines Regulatory Authority (ZAMRA) were efficient and effective in protecting and enhancing public health through the control and regulation of medicines.

## 1.2 Background

Medicines are essential to health care and should be available to all citizens<sup>38</sup>. Medicines are safely used every day to treat diseases, however, there have been adverse events over the years to prove that consumption of medicines also carries risks. It is therefore a fundamental role of government to protect and promote the health and safety of the public through a well-functioning health care system that ensures available and affordable medical products that are safe, efficacious and of assured quality<sup>39</sup>. The importance of quality medicines is identified as a global need with the Sustainable Development Goals (SDG) No.3 "Good Health and Well-being" specifically under Target 3.8 requiring all United Nations member states to achieve universal health coverage, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all by 2030.<sup>40</sup>

Medical products are essential in the prevention, diagnosis and treatment of disease. The consequences of the consumption and use of substandard and falsified medical products can be life threatening<sup>41</sup>. According to the 2018 World Health Organisation (WHO) fact sheet<sup>42</sup>, fake medicines are a challenge especially in developing countries with estimates of at least 1 in 10 of all drugs sold being false, unregistered or sub-standard. Sub-Saharan Africa is the worst hit and

<sup>&</sup>lt;sup>38</sup>Medicines Regulation in Africa: Current State and Opportunities (springer.com) 2017

<sup>&</sup>lt;sup>39</sup>https://www.wto.org/english/tratop e/trips e/techsymp 290621/gaspar pres2.pdf

<sup>40</sup>https://www.globalgoals.org/goals/3-good-health-and-well-being/

<sup>41</sup>https://www.wto.org/english/tratop e/trips e/techsymp 290621/gaspar pres2.pdf

<sup>&</sup>lt;sup>42</sup>https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products

accounts for 42% of all sub-standard drugs. The WHO global surveillance and monitoring system for sub-standard and falsified medical products also reported that 10% of low and middle-income countries including Zambia consumed drugs that were below standard, falsely labelled or simply fake. The countries collectively spend US\$30.5 billion on fake drugs which is attributed to suppliers of fake medicine taking advantage of considerable amounts of money that the countries spend on medication as well as weak medicines and allied substances regulatory systems. Weak regulatory environment does not only encourage the manufacture and sale of low quality, potentially ineffective and unsafe medicines but also acts as a barrier to quality production. The production among the countries that have reported counterfeit medications with a great number of registered medicines failing to meet the quality standards. In 2020, ZAMRA also reported an increase in the number of illegal exports, imports and transportation of medical products with seizures of assorted medicines including Lofnac tablets, Chlorpheniramine, Stopcold, Cold Care Tablets and Diclofenac due to lack of proper documentation for medicine in transit.

Sound regulatory systems play a critical role in protecting public health against use of medical products which do not meet the required standards of quality, safety and efficacy.<sup>48</sup> They also enhance proper functioning of economies and societies.<sup>49</sup> The three common pillars of medicines regulation are quality, safety, and efficacy whose detail is illustrated in Figure 1.1below:

<sup>&</sup>lt;sup>43</sup>World Health Organization. (2017). WHO global surveillance and monitoring system for substandard and falsified medical products

<sup>&</sup>lt;sup>44</sup>https://zambia.co.zm/news/headlines/2017/12/08/zambia-on-fake-drugs-listwho-says-country-among-others-spending-30bn-on-fake-drugs-annually/

<sup>&</sup>lt;sup>45</sup>https://www.wto.org/english/tratop e/trips e/techsymp 290621/gaspar pres2.pdf

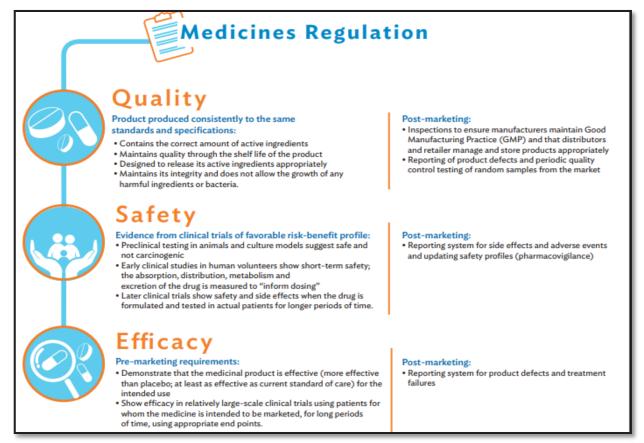
<sup>46</sup>www.daily-mail.co.zm – December 19,2017, http://www.daily-mail.co.zm/fake-drug-threat-what-to-do/

<sup>&</sup>lt;sup>47</sup> ZAMRA press statement 7<sup>th</sup> October,2020

<sup>&</sup>lt;sup>48</sup>Medicines Regulation in Africa: Current State and Opportunities (springer.com) 2017

<sup>&</sup>lt;sup>49</sup>Medicines Regulation, Regulatory Harmonization, Global Initiatives (worldbank.org)

Figure 1.1: The Three Pillars of Medicines Regulation



Source: Asian Development Bank (ADB)Briefs No. 54 April 2016 50

The Government,through the Seventh National Development Plan (7NDP), committed to increase access to quality health care through building the health system to ensure equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness. Further, the Eighth National Development Plan (8NDP) under Development Outcome No. 2 "Improved Health, Food and Nutrition" Strategy 2: "Increase Access to Quality Health Care" also emphasises the provision of quality health services to the public through ensuring availability of medicines and medical supplies among others.

The Ministry of Health (MoH), through ZAMRA, is responsible for the control and regulation of medicines in the country to ensure that medicines on the market are safe, efficacious, and of quality.

<sup>&</sup>lt;sup>50</sup> Better Regulation of Medicines Means Stronger Regional Health Security, Strengthening and Convergence of National Regulatory Agencies has Benefits beyond Country Borders 2016

<sup>&</sup>lt;sup>51</sup> Development Outcome 1,Strategy 2: Expand capacity to increase access to quality health care (7NDP)

#### 1.3 Motivation

The audit was motivated by the following:

### i. Parliamentary Interest

Concerns were raised by Parliamentarians during a debate in 2021 on Governments' position on the supply of defective drugs and on whether the defective products had since been recalled. Similarly, in a Question for Oral Answer Session on 4<sup>th</sup> May 2021, the then Minister of Health raised concern on the inadequate regulation of dangerous drugs in the country leading to widespread abuse of dangerous drugs in communities.<sup>52</sup>

#### ii. Literature Review

A study on the quality of antimalarial drugs<sup>53</sup>reported poor quality of antimalarial drugs with results showing that 10.3% of tested drugs contained less than 80% of the labeled active pharmaceutical ingredient. Further, through post-market surveillance at hospitals in three (3) provinces, ZAMRA reported that 22 out of 125 essential medicines samples tested representing 17.6% did not pass the Global Pharma Health Fund's Minilab tests in 2019.<sup>54</sup>

#### iii. Media Reports

Media reports dated 23<sup>rd</sup> February 2022 revealed that bottles of sub-standard paracetamol were distributed to Kabwe and Kasama General Hospitals and were subsequently dispensed to patients while 198 bottles were recalled and quarantined at Zambia Medicines and Medical Supplies Agency (ZAMMSA). It was further reported that some of the drugs had since been consumed and the traced patients were under observation for negative effects on their health.<sup>55</sup>

Another media report dated 21<sup>st</sup> December 2021 revealed that there were unapproved medicines in the country with a recent case of a leading socialite who was apprehended for the placement on the market of medicine without the approval of the Authority and in undesignated locations.<sup>56</sup> With the advent of the Coronavirus pandemic (COVID 19), there has also been reported widespread abuse of antibiotics and the use of other prescription drugs such as Ivermectin. In this regard, the Authority issued a Press Statement on 10<sup>th</sup> February 2021 informing the Public that despite reported widespread use of Ivermectin for the treatment and prevention of COVID 19, there was inadequate clinical evidence to support its use. <sup>57</sup>

<sup>&</sup>lt;sup>52</sup>ZAMRA recalls defective medicines – Veep – Daily Nation (dailynationzambia.com)

<sup>&</sup>lt;sup>53</sup>Controlled research on the Health and Economic impact of poor-quality antimalarial in Zambia which was conducted in July 2020

<sup>&</sup>lt;sup>54</sup>Impact of substandard and falsified antimalarial in Zambia: application of the SAFARI model | BMC Public Health | Full Text (biomedcentral.com)

<sup>&</sup>lt;sup>55</sup> The Daily Mail newspaper dated February 23<sup>rd</sup>, 2022

<sup>&</sup>lt;sup>56</sup>Press statement issued by ZAMRA on 21<sup>st</sup> December 2021

<sup>&</sup>lt;sup>57</sup>www.diggers,news – Antibiotics abuse worries Minster of Health, 22<sup>nd</sup> September 2021

There have been reported cases of pharmacies and health shops operating illegally<sup>58</sup> and reported cases of illegal importation of medicines into the country.<sup>59</sup> Several product recalls have been made with the most contentious in recent times being the Honey Bee scandal in which the MoH contracted an unregistered company to provide drugs, condoms and gloves worth over US\$ 17 million that were later certified toxic and sub-standard.<sup>60</sup> The matter is, however, in the courts of law as of November 2022.

<sup>&</sup>lt;sup>58</sup>Press statement issued by ZAMRA on 10<sup>th</sup> January 2021

<sup>&</sup>lt;sup>59</sup>ibid

<sup>&</sup>lt;sup>60</sup>www.diggers.news- MPs grill Honeybee. MoH PS, and ZAMRA over US\$ 17 Million drug scandal

## **CHAPTER 2: AUDIT OBJECTIVE AND AUDIT QUESTIONS**

#### 2.0 Introduction

This chapter highlights the main and specific audit objectives, scope and the audit questions to be answered to achieve the audit objective.

### 2.1 Main Audit Objective

To assess whether measures put in place by Zambia Medicines Regulatory Authority (ZAMRA) are efficient and effective in protecting and enhancing public health through the control and regulation of medicines.

#### 2.2 Specific Audit Objectives

- 2.2.1 To ascertain whether key regulatory processes are carried out in an efficient and effective manner; and
- 2.2.2 To establish how ZAMRA ensures strategic stakeholder alliances with key stakeholders.

#### 2.3 Audit Questions

# 2.3.1 To what extent is ZAMRA efficient and effective in the control and monitoring of medicines in the country?

- 2.3.1.1 How has the Authority ensured that the measures put in place to control medicines are efficient and effective?
- 2.3.1.2 How efficient and effective is ZAMRA in monitoring medicines on the market?

## 2.3.2 To what extent has ZAMRA ensured the formation of strategic alliances with Key Stakeholders?

- 2.3.2.1 How does ZAMRA ensure that the public is sensitised on the importance of observing regulatory requirements in order to have safe, efficacious and quality medicines on the market?
- 2.3.2.2 Have strategic alliances been formed between ZAMRA and key stakeholders, so as to develop strong collaborations?

### 2.4 Audit Scope

The audited entity was ZAMRA as it is responsible for controlling and regulating medicines. The audit focused on evaluating whether measures developed to control and regulate medicines were achieving the objective to protect and enhance public health in Zambia and was limited to human medicines. Allied substances and veterinary medicines were not part of the scope. The audit covered a period of four (4) years from January 2019 to December 2022 as it provided an adequate timeframe within which to evaluate whether the measures developed had yielded desired results.

#### 2.5 Audit Limitations

- i. Due to limited resources, the selection of wholesale, retail and hospital pharmacies including health shops was limited making the sample size less representative which increased the sampling risk. However, this was mitigated through a request for information to all the 116 Local Authorities on premises operating as pharmacies.
- ii. There was low response on the request for information from Local Authorities as only 21 out of 116 responded representing a response rate of 18%. This affected the quantity and coverage of data required for comparative analysis. As a result, the audit used the limited information provided and corroborated it with other data where available.
- iii. The subject matter was technical and required independent expertise on quality testing. This was mitigated by placing reliance on ZAMRAs expertise.

- 7 -

## **CHAPTER 3: METHODOLOGY**

#### 3.0 Introduction

This chapter presents the design of the audit specifying the target population, sample size, sampling techniques, data collection and analysis techniques employed. The audit was conducted in accordance with the International Standard of Supreme Audit Institutions (ISSAIs) 3000 and guidelines in the OAG Performance Audit Manual. The Standards require that the audit is planned in a manner which ensures that an audit of high quality is carried out in an economic, efficient and effective manner.

### 3.1 Research Design

The audit used a problem-based approach which examines, verifies and analyses the causes of particular problems or deviations from criteria. The audit adopted a mixed method of analysis that was inclusive of quantitative and qualitative approaches. The two approaches were used because of the relevance to the audit as they provided a basis for data analysis by comparing interpretations in the audit.

## 3.2 Sampling Techniques

Purposive sampling was used to select provinces and districts while regulated premises were selected at random. The selection of the population was based on a mix of regulated premises which included drug manufacturing companies, wholesale pharmaceutical companies, retail pharmacies, health shops, private hospital pharmacies as well as regulated and unregulated public premises in selected districts. Stakeholders interviewed were selected based on stakeholder mapping and degree of coordination with ZAMRA. Local Authorities were also selected based on the location of regulated premises.

#### 3.3 Sample Population and Size

Out of a total of ten (10) provinces, a sample of six (6) provinces were selected in which eighteen (18) out of sixty-six (66)<sup>61</sup> districts were purposively sampled representing 27.3%. From the selected districts, 153 premises compromising:14 health shops; 56 retail pharmacies; 10 wholesale pharmacies; 62 public hospital pharmacies; 8 registered private hospital pharmacies; and 3 drug manufacturing companies were randomly sampled. **Appendix 1** for details.

<sup>&</sup>lt;sup>61</sup>The 6 provinces comprised 66 districts

#### 3.4 Data Collection Methods

In order to obtain sufficient evidence to support the audit findings, various methods were employed to collect data from both ZAMRA and stakeholders. The methods included interviews, document review and physical inspections. The methods of data collection are detailed below:

#### 3.4.1 Interviews

A total of 200 interviewees were engaged during the audit. Semi-structured interviews were conducted with ZAMRA, key stakeholders and Local Authorities to confirm information gathered from document reviews and obtain recommendations to address underperformance. See **Appendix 2a, 2b and 2c.** 

#### 3.4.2 Site Visitations

A selection of regulated premises were inspected to verify adherence to pharmaceutical guidelines as well as observe conditions under which medicines are manufactured, stored and dispensed. Inspections were also used to corroborate information obtained through interviews and document review. Questionnaires were administered to relevant personnel at regulated premises to confirm adherence to pharmaceutical guidelines while pictorial evidence was obtained where necessary. See **Appendix 2d.** 

#### 3.4.3 Document Review

Various documents were reviewed to obtain reliable audit evidence in order to draw reasonable conclusions and recommendations. See **Appendix 3**.

#### 3.4.4 Data Analysis

The audit obtained quantitative and qualitative data from interviews, document reviews, request for information and, noted information from direct observations and physical inspection. This was subjected to relevant analysis such as descriptive analysis, trend analysis and relating the information to generate reasonable conclusions.

## **CHAPTER 4: DESCRIPTION OF THE AUDIT AREA**

#### 4.0 Introduction

The chapter discusses the mandate of ZAMRA, organisational structure, funding details and key stakeholders. It also describes how systems at the Authority are intended to operate.

#### 4.1 Mandate

The Authority draws its mandate from the Medicines and Allied Substances Act (MASA) No. 3 of 2013 and is responsible for medicines regulation in Zambia.

### 4.2 Roles and Responsibilities

The following are the functions of ZAMRA<sup>62</sup>:

- a) Granting of pharmaceutical licenses and Marketing Authorisation;
- b) Inspection of premises used for the purpose of manufacturing, distribution, sale, importation or exportation of medicines or allied substances or for any other purposes regulated under the MASA No. 3 of 2013;
- c) Regulate and control the manufacture, importation, exportation, distribution and sale of medicines;
- d) Registration and regulation of pharmacies and health shops;
- e) Establishment, maintenance and enforcement of standards relating to the manufacture, importation, exportation, distribution and sale of medicines;
- f) Post-marketing surveillance;
- g) Establishment, maintenance, and enforcement of standards for drug quality control laboratories; and
- h) Collaboration with the corresponding medicines regulatory authorities in other countries.

#### 4.3 Organisation Structure

The Zambia Medicines Regulatory Authority is headed by a Director General (DG) who is the Chief Executive Officer (CEO) appointed by the Board. Figure 4.1 below shows the Organisation Structure of ZAMRA.

MASA No. 3 of 2013 Part II Section(5)<sup>62</sup>

Assistant Internal Auditor Internal Auditor Manager/Board Secretary Legal Officer Legal Analyst -Microbiology Principal Officers Chief Director Laboratory Services Laboratory Quality Assurance officer Chief Analyst -Physico Chemical Principal Officers Assistant Director -LSE Principal Officers Director Medicines Control Director General Board Assistant Director -MA Principal Officers Chief Accountant Accountant Senior Procurement Officer Director Corporate Services Senior HRA Officer Figure 4.1 - ZAMRA Organogram Head HRA Principal ICT Officer Senior Public Relations Officer Relations Officer Public Quality Assurance Officer Senior Quality Assurance Officer

Source: ZAMRA Organisation Structure 2022

As indicated in the organisation structure above, the DG is supported by Directors of Medicines Control, Corporate Services and Laboratory Services. The three directorates and their functions are described below:

#### **4.3.1** Corporate Services Directorate

The Directorate is responsible for managing human, financial, administrative and logistical support services to enhance operations of the Authority. The Directorate is also responsible for providing secretarial and legal services.

#### 4.3.2 Medicines Control Directorate

The Directorate is responsible for effectively managing the registration of products, undertaking post marketing, licensing, surveillance and controlling the conduct of clinical trials in order to achieve compliance to statutory regulations. It is further broken down into two sections namely: Marketing Authorisation and Licensing, Surveillance and Enforcement. The sections are headed by an Assistant Director who report directly to the Director. The Licensing, Surveillance and Enforcement Section also has presence in three (3) regional offices namely Copperbelt, Eastern and Lusaka with sub-regional offices in Kasama, Solwezi and Livingstone.

## 4.3.3 Laboratory Services Directorate

The Laboratory Services Directorate hosts the National Drug Quality Control Laboratory (NDQCL). It is responsible for the provision of specialised laboratory services to guarantee the quality, efficacy and safety of pharmaceutical products thereby safeguarding public health. It has two main functional sections namely: Physical-Chemical (PC) and Microbiology (MB) units, with each unit headed by a chemist/ scientist.

#### 4.4 Funding Arrangements

The Authority is funded from fees charged, bank interest or interest on loans, grants received from the Government and donor support from Cooperating Partners (CPs). The budget for operations and the amounts released during the period under review are as shown in Table 4.1.

Table 4.1: Funding Arrangements

	Sources of income						
Year	Income fees (K)	Other Cooperating Partners (K)	Other Income (Interest) (K)	Total income (K)	Budgeted income (K)	Surplus/ (Deficit) (K)	Expenditure (K)
2019	56,188,626.00	3,661,982.00	8,536,536.00	68,387,144.00	61,848,157.48	6,538,986.52	74,778,422.00
2020	78,357,404.37	5,253,403.00	22,967,629.82	106,578,437.19	101,738,271.02	4,840,166.17	86,198,464.96
2021	105,042,729.74	5,019,527.83	33,777,511.00	143,839,768.57	94,525,324.25	49,314,444.32	97,372,808.26
Jun-22	55,385,577.08	-	1,727,917.71	57,113,494.79	121,610,270.32	-64,496,775.53	41,601,444.72
Overall Total	294,974,337.19	13,934,912.83	67,009,594.53	375,918,844.55	379,722,023.07	-3,803,178.52	299,951,139.94

Source: ZAMRA Medium Term Expenditure Framework (MTEF) 2019 – 2022 Reports and ZAMRA 2019 and 2020 Annual Reports

As seen from Table 4.1 above, ZAMRA received a total income of K375, 918,844.55 from income fees and other Cooperating Partners (CPs) against a total budgeted income of K379,722,023.07 from January 2019 to June 2022. From the total income received, ZAMRA expended a total amount of K299, 951,139.94 as at June 2022. Further, ZAMRA accumulated surpluses ranging from K6, 538,986.52 to K49, 314,444.32 between 2019 and 2021.

### 4.5 Key Stakeholders

ZAMRA coordinates with a number of stakeholders in the discharge of its mandate as detailed below:

#### 4.5.1 World Health Organisation

The World Health Organisation (WHO) coordinates with ZAMRA through the issuance of pharmaceutical norms and standards which are grouped into; development, production, distribution, inspection, quality control, regulatory standards and specific texts for the prequalification of medicines. The norms and standards are prepared through a vast global consultative process involving WHO member states, National Medicines Regulatory Authorities (NMRAs) and international agencies.

### 4.5.2 Health Professionals Council of Zambia

The Health Professionals Council of Zambia (HPCZ) is a statutory regulatory body established by the Health Professions Act No. 24 of 2009 of the Laws of Zambia. HPCZs'role is to register and regulate all health practitioners which include pharmacists and pharmacist technologists. The Council also licenses all public and private health facilities. In addition, HPCZ and ZAMRA undertake joint inspections when need arises for example complaints on pharmaceutical practices.

### 4.5.3 Zambia Revenue Authority

The Zambia Revenue Authority (ZRA) is charged with the responsibility of collecting revenue under the policy direction of the Minister of Finance. It is also responsible for administering trade taxes, fees and charges and also enforces regulatory control on imports, exports and goods in transit. Through the ASCYUDA System, ZRA informs ZAMRA when imports of medicines are received at points of entry for purposes of inspections.

### 4.6 Systems Description

As a regulator of medicines, the Authority undertakes key processes in the execution of its mandate which include: Market Authorisation; Pharmacovigilance; Licensing; Inspections; Control of Imports and Exports of Medicines; Enforcement and; Quality Control.<sup>63</sup>

#### 4.6.1 Market Authorisation

The grant of Marketing Authorisation(MA) is done in the following steps<sup>64</sup>:

- i. Authority receives an application within one (1) day which is reviewed by the Holding Medicines Committee;
- ii. Screening and acknowledgement of receipt of applications within five (5) working days;
- iii. Evaluation of new applications and submission of queries by the Registration Officers within 155 days;
- iv. Evaluation of first round of responses and providing feedback within thirty (30) days by Registration Officer;
- v. The Registration Officer evaluates second round of responses, compiles the report and submits the application to Technical Committee within thirty (30) days;
- vi. Within thirty (30) days, the Technical Committee deliberates on the application and summary of submission. If satisfied, the Technical Committee provides recommendations for approval of application which is sent to the Director General (DG) who then issues the MA number through the system.

#### 4.6.1.1 Pharmacovigilance

The Principal Surveillance Officer (PSO) ensures that all received pharmacovigilance reports are assigned to officers for assessment, investigation and recording. The Surveillance Officer (SO) records pharmacovigilance reports, maintains vigilance registers including electronic database, assesses causality, investigates reports, drafts and files the reports. The SO enters all received reports in the National Pharmacovigilance Database after which risk assessment is conducted using appropriate tools. All reports are treated on First in First out (FIFO) basis however, high risk reports are reported to the DMC immediately for urgent action.

<sup>&</sup>lt;sup>63</sup>Strategic Plan 2020-2021 and Minutes from interviews

<sup>&</sup>lt;sup>64</sup>ZAMRA Service Charter

#### 4.6.2 Licensing

The PRO is responsible for reviewing, endorsing and assigning of applications for establishing pharmaceutical outlets. The applicant tenders an application which is then confirmed as being completed by the Administrative Officer (AO) after which license fees are paid. The application is then forwarded to the PRO who records it in the applicable register and assigns a unique identification number and competent inspector to assess the application. The inspector then assesses the application according to the appropriate checklist. Where information is inadequate or incomplete, the inspector communicates with the applicant using Additional Information Form II. Once additional information is received, the inspector reassesses the information within ten (10) working days. The inspector approves the application by appending his signature on the application form and plans an appropriate inspection. When an inspection meets the required standard, a license is granted. However, if there are significant flaws the applicant is requested to address the changes upon which a verification inspection is conducted. If satisfactory, a license is granted.

#### 4.6.2.1 Control of Import and Export of Medicines at Ports of Entry

The Director General (DG) approves and endorses import/export permits after which the Licensing Officer (LO) will process the permits and provide any necessary information to the inspectors at points of entry. Payments are then made in respect of the processed permits after which the Assistant Inspector (AI) at the appropriate site reviews submitted documents and conducts physical inspections of the medicines received.

#### 4.6.2.2 Enforcement

The Board appoints suitably qualified persons to be inspectors for purposes of ensuring compliance with the MASA. An inspector with an identification card, in the prescribed form then proceeds to carry out inspections in registered premises. The inspector is expected to enforce the provisions of the MASA and on the authority of a warrant, enter any pharmacy, health shop, agro-veterinary shop, container, vessel, vehicle, aircraft or other conveyance that the inspector has reasonable grounds to believe is used for the commission of an offence or purposes contrary to the provisions of the MASA. The inspector has the right to search any person on the premises if there are reasonable grounds to believe that the person has possession of an article, document, record or medicine that has a bearing on an investigation after which a seizure may take place. The seized items may then be subjected to testing, examination or analysis.

#### 4.6.3 Quality Control

The DMC approves a Sampling Plan after which the SO prepares an Implementation Plan which contains: product to be sampled; dosage form and storage conditions; minimum number of dosage units to be collected per sample; number of samples to be sampled per site; sampling site; and timeframe for sampling. The SO consults the laboratory on the availability of inputs to be used in testing of samples. If inputs are available, samples are collected and subjected to analysis by the NDQCL.

### **CHAPTER 5: AUDIT CRITERIA**

#### 5.0 Introduction

This chapter presents the sources of criteria and criteria that was used to assess the measures put in place for the control and regulation of medicines in Zambia. Criteria are reasonable and attainable standards of performance against which economy, efficiency and effectiveness of activities can be assessed.

#### 5.1 Sources of Criteria

The criteria were drawn from the following sources:

- The Medicines and Allied Substances Act No. 3 of 2013
- The National Health Policy 2012
- ZAMRA Public Relations Policy 2021
- ZAMRA Strategic Plan 2019 2021
- ZAMRA Pharmacovigilance Reference Manual Second Edition March 2020
- ZAMRA Annual Work Plans 2019 to 2021
- ZAMRA Standards of Pharmaceutical Practice
- ZAMRA Service Charter
- International Organisation of Standardisation (ISO) 17025
- World Health Organisation Good Practices for Pharmaceutical Quality Control Laboratory (WHOGPPQCL)

# 5.2 Extent to which ZAMRA is efficient and effective in the control and monitoring of medicines in the country.

#### **5.2.1** Effectiveness of Control Measures

#### 5.2.1.1 Market Authorisation

The MASA prohibits a person to place on the market, advertise, market, manufacture, sell, import, supply, administer or deal in any manner with any medicine without a MA issued by the Authority. It further requires that a person who intends to deal with medicine to apply for a MA from the Authority.<sup>65</sup>

#### **5.2.1.2** Importation of Medicines

The MASA stipulates that a person shall not import any medicine without an import permit.<sup>66</sup>

<sup>65</sup> MASA No. 3 of 2013, Part V Section 39(2)

<sup>&</sup>lt;sup>66</sup>MASA No. 3 of 2013 Part IV Section 35(1)

#### 5.2.1.3 Licensing

The MASA prohibits a person who does not have a permit to operate either on that person's own behalf or on behalf of another person, a pharmacy and health shop.<sup>67</sup> In addition, a person shall not manufacture, distribute or deal in any medicine without a pharmaceutical license.<sup>68</sup>

#### **5.2.2** Monitoring of Medicines

## **5.2.3** Inspection of Regulated Premises

ZAMRA should establish, through periodic formal inspections and spot checks, that all license holders operate within the terms of their licenses and observe prescribed regulations and officially recognised standards of practice, that is to say:- pharmaceutical manufacturers comply with good manufacturing practice; pharmaceutical importers observe good pharmaceutical import and warehousing practice; retail pharmacies observe good pharmacy practices; and hospital pharmacies observe good hospital pharmacy practice. Further, targeted regular inspections of manufacturers along the supply chain can remove poor quality medicines from the market to address substandard and counterfeit health products. To

#### 5.2.4 Enforcement

According to the MASA, the Authority must establish, maintain and enforce standards relating to the manufacture, importation, exportation, distribution and sale of medicines.<sup>71</sup>

The Authority may order the closure of a pharmacy where; the pharmacy contravenes the terms and conditions of registration in a manner that presents danger or imminent harm to members of the public; the pharmacy is not registered under the MASA; or the pharmacy contravenes the provisions of the MASA or any other relevant law. The MASA further requires the Authority to give the pharmacy written notice of the violation where it receives an inspection report indicating that a pharmacy is not compliant with the requirements of the MASA or its certificate of registration or is offering services more than those permitted to the pharmacy. A pharmacy shall then within fourteen (14) days of service of the notice provide the DG with a written plan of correction of the violation, indicating a schedule of dates by which corrective action shall be taken. Where the plan of correction submitted by a pharmacy is rejected by the DG, the Authority shall revoke the certificate of registration and order the closure of the pharmacy. <sup>72</sup>

<sup>&</sup>lt;sup>67</sup> MASA No 3. of 2013 Part III Section 14(1)

<sup>&</sup>lt;sup>68</sup>MASA No 3. of 2013 Part IV Section 33, 34

<sup>&</sup>lt;sup>69</sup> ZAMRA Standards of Pharmaceutical Practice.

<sup>&</sup>lt;sup>70</sup>https://www.adb.org/sites/default/files/publication/184392/better-regulation-medicine.pdf

<sup>71</sup> MASA No.3 of 2013 Part II Section 5 (i)

<sup>&</sup>lt;sup>72</sup>MASA No.3 of 2013 Part III Section 24 (1) – (5)

#### **5.2.5** Post Market Surveillance

The MASA mandates an inspector at any reasonable time, and on the authority of a warrant, to enter any premises, pharmacy, health shop, container, vessel, vehicle, aircraft or other conveyance that the inspector has reasonable grounds to believe is used for the commission of an offence or purposes contrary to the provisions of this Act and take samples of any medicine as maybe necessary for the purposes of testing, examination or analysis.<sup>73</sup>

#### 5.2.6 Pharmacovigilance

The Authority shall make regulations for monitoring the safety of medicines as well as recalls or withdrawal of medicines that do not meet the prescribed standards of quality, efficacy, and safety<sup>74</sup>. MA holders should maintain an appropriate pharmacovigilance system for monitoring, detecting and reporting Adverse Drug Reactions (ADRs) and the performance of products granted marketing authorisation<sup>75</sup>. Retail pharmacies, health centres and hospitals are also required to maintain a register for ADRs, based on observations of patients or laboratory results.

## 5.2.7 Laboratory Services

The Authority shall establish the NDQCL and shall use the Laboratory to among others:

- a) verify the safety, quality and efficacy of medicines which are manufactured or imported into the country by persons who are authorised or licensed under the MASA to examine, analyse and conduct research on medicine;
- b) provide laboratory services to the general public; and
- c) perform such other functions relating to the analysis of medicines as it considers necessary.<sup>76</sup>

According to the ZAMRA Service Charter, Certificates of Analysis should be issued within twenty-one (21) days broken down as follows: completed request form and sample(s) within three (3) working days; provide feedback on request within three (3) working days and issue Certificate of Analysis within fifteen (15) working days.<sup>77</sup>

Further, the International Operations of Standardisation (ISO) 17025 provides that the laboratory should have a procedure for monitoring the validity of results. The resulting data should be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include where appropriate but not limited to use of reference or quality control materials. The laboratory shall ensure that measurement results are traceable to the international system of units through calibration provided by a competent laboratory.

<sup>&</sup>lt;sup>73</sup>MASA No 3 of 2013 Part VIII Section 55 (4)(f)

<sup>&</sup>lt;sup>74</sup>MASA No. 13 of 2013 Part IX Section 69(g)

<sup>&</sup>lt;sup>75</sup> Statutory Instruments No.42 Terms and Conditions of the Marketing Authorisation 22nd November, 2019

<sup>&</sup>lt;sup>76</sup>MASA No. 3 of 2013 Part VII Section 54. (1) (2)

<sup>&</sup>lt;sup>77</sup>ZAMRA Service Charter

## 5.3 Extent to which ZAMRA has Formed Strategic Alliances with Key Stakeholders

MASA requires that ZAMRA collaborates with other corresponding National Medicines Regulatory Authorities (NMRAs)in other countries. <sup>78</sup>In addition, in the ZAMRA Strategic Plan 2019- 2021, one of the Authority's key result areas is improved stakeholder engagement so as to strengthen local and international strategic partnerships. <sup>79</sup> Further, one of the objectives of the National Health Policy is to ensure the availability of safe, efficacious, good quality and affordable essential medicines and other medical commodities by putting in place mechanisms to ensure adequate coordination of roles being played by the many partners in the pharmaceutical industry. <sup>80</sup> Lastly, NMRAs are required to collaborate with national, regional, international and other stakeholder so as to help in the exchange of information and promotion of international best practice. <sup>81</sup>

<sup>&</sup>lt;sup>78</sup> MASA No. 3 of 2013 Part II, Section 5 (m)

<sup>&</sup>lt;sup>79</sup> Zambia Medicines Regulatory Authority (ZAMRA) Strategic Plan 2019 - 2021

<sup>&</sup>lt;sup>80</sup> National Health Policy 2012

<sup>81</sup> ZAMRA Public Relations Policy 2021

## **CHAPTER 6: FINDINGS**

#### 6.0 Introduction

The chapter highlights the findings generated by the audit by ensuring sufficient and appropriate evidence, verifying the problem(s) and analysing causes to the problems based on relevant criteria.

# 6.1 Extent to which ZAMRA is efficient and effective in the control and monitoring of medicines in the country.

#### **6.1.1** Effectiveness of Control Measures

#### 6.1.1.1 Marketing Authorisation

As a measure to control and regulate the use of medicines, the Authority issues marketing authorisation to anyone intending to place medicine and advertise medicines on the market. The following were observed:

### 6.1.1.1.1 Granting of Marketing Authorisation

The MASA prohibits a person to place on the market, advertise, market, manufacture, sell, import, supply, administer or deal in any manner with any medicine without marketing authorisation. It further requires that a person who intends to deal with medicine apply for a marketing authorisation from the Authority.<sup>82</sup>

During the period under review, ZAMRA received applications for grant of MAs. See figure 6.1 below:

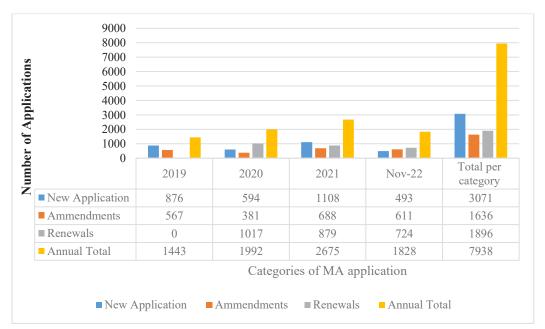


Figure 6.1: Statistics of Number of Marketing Authorisations received by the Authority

Source: ZAMRA MA Annual Reports 2019 to 2021

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<sup>82</sup> MASA No. 3 of 2013, Part V Section 39 (2)

As can be seen in Figure 6.1 above, ZAMRA received MA applications totaling 1443 in 2019, 1992 in 2020, 2675 in 2021 and 1828 as at November 2022. The figure also shows an upward trend in the total categories for MA applications received from 1443 to 1992 in 2020 representing 38% and in 2021 from 1992 to 2675 representing 35.5%. However, as at November 2022 there was reduction from 2675 to 1828 representing 31.66%.

The audit further etablished that during the period under review, the MA section evaluated and granted MAs as shown in Figure 6.2 below:

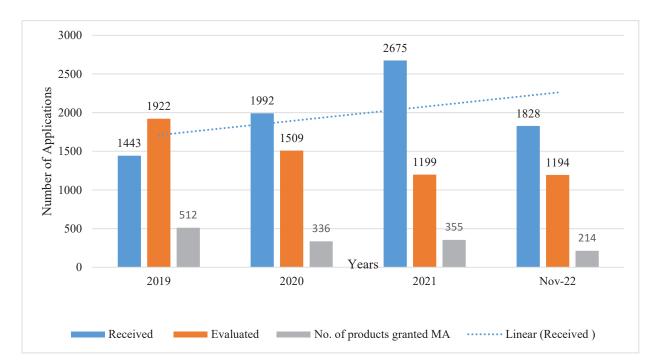


Figure 6.2: Marketing Authorisation Applications Evaluated and Granted

Source: ZAMRA MA Annual Reports 2019 to 2021

As can be seen in figure 6.2 above, ZAMRA had not evaluated all applications received during the period under review with an exception of 2019 where all applications were evaluated including a carryover of 479 from 2018. In the period 2020 and 2021 ZAMRA had pending applications of 483 and 1476 respectively. Figure 6.2 also shows that there were low numbers of MA granted during the period under review with the analysis showing a downward trend in the number of MA granted from 512 in 2019 to 214 as at November 2022. A further comparison of applications evaluated against MA granted shows a downward trend in MA granted. Out of the 1992 evaluated, 512 MA were granted in 2019 representing 25.7 %, in 2020, 1509 were evaluated out of which 336 MA were granted representing 22.27% and in 2021, out of the 1199 applications evaluated 355 MA were granted representing 29.6%.

The reason for evaluating all applications received in 2019 including the 479 carryover from 2018 was attributed to the three (3) scheduled intensive evaluation retreats which were held from 27<sup>th</sup>May to 7<sup>th</sup> June 2019; 8<sup>th</sup> to 19<sup>th</sup> July 2019 and from 2<sup>nd</sup> to 13<sup>th</sup> September 2019. 8<sup>3</sup>The increased number of evaluated product applications in the year 2019 was also attributed to the implementation of alternative processes for evaluating applications especially the use of abridged evaluation template for old or simple molecules with good and established safety profile, an example of paracetamol which is an old and stable molecule. However, the reason for ZAMRA not being able to evaluate all applications in 2020 and 2021 was attributed to an increase of 34.3% in the number of applications received which was not commensurate with the number of staff handling the applications.

Further, the low grant of MAs was also attributed to low staffing under the MA Section as well as delays by applicants to provide Pharmacopiers which are used in the evaluation of medicines. In this regard, the audit established that ZAMRA had an establishment of two (2) members of staff under the MA Section who were required to evaluate one (1) dossier, three (3) additional information, two (2) renewals as well as three (3) amendments on a weekly basis. It was further established that a dossier on average contained 40,970 pages for four fixed dose combination; 12,215 pages for three fixed dose combination; 16,893 pages for two fixed dose combination; and 16,891 pages for one fixed dose combination.

Failure to process MAs within the stipulated time poses a risk of medicines not being readily available on the market which may result in shortagesin health facilities. It also increases the risk of medicines whose safety, quality and efficacy have not been established being available illegally on the market as seen in Table 6.1.

Table 6.1: Unauthorised Medicines

No.	Name of Pharmacy	Details Of Unauthorised Medicines
	Submission from ZAMRA	
01		A total of 34 bottles labelled in chinese language each containing 45 tablets were seized
02	Motala Pharmacy	Obtaining Ivermectin from unauthorised suppliers and selling without Marketing Authorisation
03	grocery shop	Maxdol an unregistered product was seized
04	Lusaka Pharmaceuticals Limited	dealing with medicines without Marketing Authorisation
	Field inspections	
05	Ndola and Lusaka	A total of 500 bottles of multi-purpose care solution seized during physical inspection in June 2022
06	Freshview Pharmacy in Mongu	Gonorrhea Tea seized in Lusaka at at the time of physical inspection in June 2022
07	Chipata Chemist Limited	Obtaining un approved medicines (Ivermectin) from unauthorised suppliers Chipata and selling medicines (Ivermectin) without Marketing Authorisation

Source: Performance Audit 2022

<sup>83</sup> ZAMRA April to September 2019 progress report

In response, the Authority stated that they were in the process of recruiting additional assessors in marketing authorisation. Further, the Authority stated that they were in the process of reviewing the organisation structure to address the shortfall in number of assessors.

#### **6.1.1.2** Importation of Medicines

The screening of applications for the import of medicines is targeted at ensuring that only authorised products are available on the market as one of the strategies to protect the public from substandard and falsified products.<sup>84</sup>

A review and analysis of ZAMRA database for import permits revealed that there were 2,741 applications in 2019, 3,831 in 2020 and 5,101 in 2021. See figure 6.3 below showing the trend of import permits processed from 2019 - 2021.

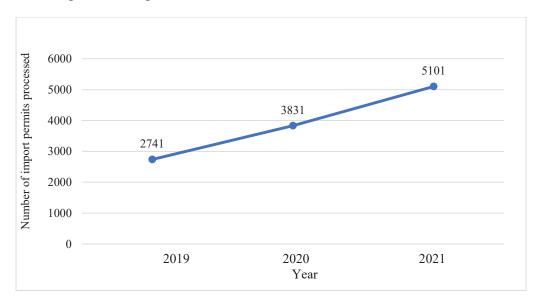


Figure 6.3: Import Permits Processed from 2019 - 2021

Source: OAG Performance Audit Data Analysis -2022

As seen in figure 6.3 above, there was an upward trend in the number of import permits processed between 2019 and 2021. The observed upward trend in the number of applications for permits that were processed was due to increased demand from: the growing Zambian population; number of products registered and licensed pharmaceutical establishments.

LA

<sup>84</sup> ZAMRA Annual Report 2019

However, despite the Authority processing 11,633 import permits, the audit established the following deficiencies as detailed below:

# 6.1.1.2.1 Importation of Medicines without a Permit

The MASA stipulates that a person shall not import medicine without an import permit. 85 The audit established that ZAMRA had improved monitoring the importation of medicines transported by freight companies. This was through collaboration between ZAMRA and ZRA by use of ASCYUDA WORLD which had modules that prompted the Authority to undertake inspections for pharmaceutical related products at ports of entry.

However, it was observed that there were weaknesses in monitoring the importation of medicines that were transported by other modes such as buses and private vehicles. This was as a result of ZAMRA having physical presence in only three (3) out of forty-seven (47) ports of entry which posed a risk of counterfeit or sub-standard medicines entering the country without detection. In addition, an analysis of summary court cases obtained from the Authority for the period 2019 to June 2022 showed that there were seven (7) court cases in 2019, two (2) cases in 2021while as at June 2022 there was only one (1) case of seized medicines imported without a permit. See **Appendix 4** for details.

Further, physical inspections revealed that there were unauthorised products being sold on the market. For example, Care Solution an unregistered product, was sold in pharmacies such as M Care and AB pharmacy in Lusaka and Ndola respectively as a purported multipurpose medication. Inspections at Chirundu border also revealed that unauthorised products such as health boosters were quarantined at the port of entry following attempts by individuals to smuggle the health boosters. Further, Fresh view pharmacy in Mongu had unauthorised products which included thirteen (13) boxes x 40g Tonic Tea - I love you, five (5) boxes x 40g Gonorrhoea Tea, and two (2) boxes x 40g Lemon slimming tea among others. Figures 6.4 and 6.5 below show the unauthorised products that were seized during physical inspections.

<sup>85</sup> MASA No. 3 of 2013 Part IV Section 35(1)

Thé de sim au Lemon

Nouvera Conceptor The Buvant Sain

Lemon Stinthing Tea

Thé de sim au Lemon

Lemon Stinthing Tea

Thé de sim au Lemon

Thé de sim au Le

Figure 6.4: Seized Unauthorised Products at Fresh View Pharmacy in Mongu

Source: OAG Performance Audit Field Data 2022



Figure 6.5: Seized Care Solution at AB Pharmacy in Ndola

Source: OAG Performance Audit Field Data 2022

The presence of illegal medicines on the Zambian market was attributed to weak enforcement by the Authority due to lack of physical presence at all ports of entry which posed a risk of counterfeit or sub-standard medicines entering the country.

In response, the Authority stated that they were considering delegating part of the inspectorate functions to Local Authorities in order to enhance enforcement.

# 6.1.1.3 Registration of Retail Pharmacies, Health shops, Wholesale Pharmacies, Public and Private Hospital Pharmacies

The MASA prohibits a person who does not have a permit to operate either on that person's own behalf or on behalf of another person, a pharmacy and health shop.<sup>86</sup> In addition, a person shall not manufacture, distribute or deal in any medicine without a pharmaceutical license.<sup>87</sup>

An analysis of the ZAMRA registration database revealed that there were a total of 1314 registered premises countrywide which included 175 wholesale pharmacies, 952 retail pharmacies, and 143 health shops as of May 2022. ZAMRA had further registered 9 public hospital pharmacies out of a total of 3,261 representing 0.28% contrary to the MASA Act No. 3 of 2013 which requires the registration of all pharmacies. Additionally, ZAMRA registered a total of thirty five (35)out of eighty (80) private hospital pharmacies representing a registration rate of 41.2%. The audit further established that the Authority recorded new registration of premises per annum as shown in Table 6.2 below:

Table 6.2: Number of New Registrations 2019 - 2022

Establishment Type	2019	2020	2021	2022
Retail Pharmacy	161	176	217	Not provided
Hospital Pharmacy - Public	1	1	1	Not provided
Hospital Pharmacy - Private	9	3	2	Not provided
Wholesale Pharmacy	100	30	35	Not provided
Health Shop	8	29	89	Not provided
Drug Manufacturing Companies	10	1	0	Not provided
Total	289	240	344	Not provided

Source: ZAMRA Database 2022

As can be seen from table 6.2 above, there was an upward trend in the registration of retail pharmacies as well as health shops which showed an increase from 161 to 217 retail pharmacies

<sup>&</sup>lt;sup>86</sup> MASA No. 3 of 2013 Part III Section 14(1)

<sup>87</sup>MASA No. 3 of 2013 Part IV Section 33, 34

representing an increase of 34.8%. The table also shows a significant increase in health shop registration from eight (8) in 2019 to eighty-nine (89) in 2021 representing an increase of 1012.5%. The increase was attributed to heightened sensitisation on health shop registration during 2020. There was however a downward trend in the registration of wholesale pharmacies due to the negative effects of COVID 19 which affected travel and import restrictions during the pandemic. In as much as there was an overall increase in the registration of premises from 289 in 2019 to 344 in 2021 representing a percentage increase of 19%, ZAMRA had not registered all premises operating as pharmacies in the country. The following observations were made:

#### 6.1.1.3.1 Wholesale Pharmacies and Drug Manufacturing Companies

Analytical reviews from the ZAMRA registration database revealed that there were 175 wholesale pharmacies and 11 local drug manufacturing companies that were registered with ZAMRA as of May 2022. **Appendix 5** refers. The audit established that all wholesale pharmacies and drug manufacturing companies were registered with the Authority and there were no reported unregistered wholesale pharmacies and drug manufacturing companies operating during the period under review. The level of compliance was attributed to the low numbers of wholesale pharmacies and drug manufacturing companies as well as the stringent measures that wholesale pharmacies and drug manufacturing companies were subjected to which included import permits for drugs, license renewals every two (2) years as well as the requirement for pharmacies to procure medicines from only registered wholesale pharmacies.

#### 6.1.1.3.2 Retail Pharmacy and Health Shop

#### i. Premises operating without a Certificate of Registration and Health Shop Permit

The audit established that some retail pharmacies and health shops operated without a certificate of registration and health shop permit respectively. In this regard, data analysis of summary court cases for the year 2019 to June 2022 showed that the Authority had prosecuted 113 cases. Figure 6.6 below shows the trend of premises prosecuted for operating without a certificate of registration and health shop permit from ZAMRA for the period 2019 to June 2022.

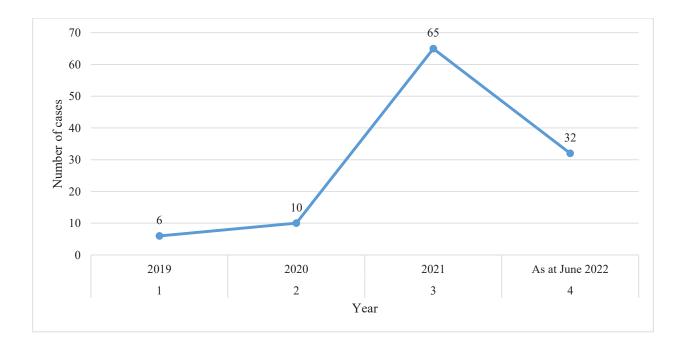


Figure 6.6: Prosecuted Retail Pharmacies and Health Shops 2019 – June 2022

Source: OAG Performance Audit Data Analysis 2022

From figure 6.6 above, it can be seen that there was an increase in the number of unregistered retail pharmacies and health shops prosecuted from six (6) in 2019 to sixty-five (65) premises in 2021 representing an increment of 983%. As at June 2022, there were thirty-two (32) unregistered retail pharmacies and health shops prosecuted.

Further, a comparison of the ZAMRA registration database to data provided by twenty-two (22) Local Authorities (LAs) (See **Appendix 6**) on premises issued with business permits to operate pharmaceutical businesses for the period 2019 to 2021, revealed that, from a total number of 351 pharmacies and health shops granted business permits, 193 were registered with ZAMRA representing 53% registration. See **Appendix 7**. The audit further established that non-registration of premises resulted from low collaboration between LAs and the Authority in that there was no information exchange mechanism between ZAMRA and the LAs which would allow the Authority to capture business permits related to pharmaceutical business. Another reason for unregistered premises was attributed to lack of enforcement as the Authority was not present countrywide. Consequently, there is a risk to public health as unregistered premises may be operating against pharmaceutical guidelines.

# ii. Public and Private Hospital Pharmacies

The audit established that there were 9 out of 3,261 public hospital pharmacies and 35 out of 80 private hospital pharmacies registered with ZAMRA. In addition, from 62 public hospital pharmacies inspected, only Ndola Teaching Hospital and Mazabuka General Hospital were registered with ZAMRA while out of eight (8) private hospital pharmacies visited, six (6) were registered with ZAMRA. See Appendix 8

The reasons for non-registration of premises namely retail, health shops, public and private hospital was attributed to among others lack of physical presence by ZAMRA in many jurisdictions and inadequate inspectors to enforce the registration of premises. The LAs interviewed attributed the reason for non-registration of premises to the processes of acquiring a license from ZAMRA. The process required a business permit (which was granted by LAs after fulfilling certain conditions) as a pre-requisite of which once granted, some pharmaceutical businesses commenced operations without obtaining certification from ZAMRA. The other reason was attributed to there being no requirement for LAs to submit to ZAMRA a list of businesses that had been granted business permits under pharmaceutical business. For instance, from a total number of 351 pharmacies and health shops granted business permits by LAs, 193 were registered with ZAMRA. It was further established that ZAMRA did not have representation on the Local Authority Public Health Committee which deliberates, approves and makes recommendations on public health matters. The Committee also provides information obtained from public health inspections which inleude pharmaceutical premises. This resulted in ZAMRA being unaware of premises that were granted business permits to operate as pharmacies and healthshops.

Failure to register premises resulted in pharmaceutical premises operating without due regard to set pharmaceutical guidelines. This was confirmed through interviews with LAs that during their public health inspections, premises were found with expired medicines on the shelves, did not have thermometers, artificial lighting and ventilation, and had dusty shelves and leakages in ceilings. It was further reported that despite LAs making recommendations on the reported shortcomings, it was not within the LAs mandate to follow up on pharmaceutical matters whose responsibility was with ZAMRA. In addition, due to lack of collaboration, LAs did not report the public health inspection findings to ZAMRA. This was also confirmed through a review of Public Health Inspection Reports for the period 2019 to 2022 for Kapiri Mposhi, Chipangali, Nyimba, Sinda Town Councils and Chadiza, Chinsali, Mazabuka and Shangombo District Councils.

Further, physical inspections revealed that from the sixty-two (62) public health facilities visited, Mazabuka General Hospital and Ndola Teaching Hospital which were registered hospitals adhered to a greater extent to the guidelines put in place by ZAMRA. However, the following deficiencies were noted:

- i. Non-pharmaceutical personnel dispensing medicines infourteen (14) health facilities;
- ii. Poor ventilation which compromised the quality and efficacy of medicines;

- iii. Lack of expired drug register and area which led to some expired medicines being comingled with usables and failure to track disposal of expired medicine; and
- iv. Non-updating of dangerous drug registers which made it difficult to trail usage of dangerous drugs. See **Appendix 9** for details.

# **6.1.2** Monitoring of Medicines

#### **6.1.2.1 Inspection of Regulated Premises**

ZAMRA should establish, through periodic formal inspections and spot checks, that all license holders operate within the terms of their licenses and observe other prescribed regulations and recognised standards, that is to say:- drug manufacturing companies comply with good manufacturing practice; pharmaceutical importers observe good pharmaceutical import and warehousing practice; pharmaceutical wholesale dealers observe good pharmaceutical warehousing and wholesaling practices; that retail pharmacies observe good pharmacy practices; and that hospital pharmacies observe good hospital pharmacy practice. Further, targeted regular inspections of manufacturers along the supply chain can remove poor quality medicines from the market to address substandard and counterfeit health products. 89

A review of ZAMRA Annual Reports for the period under review revealed that monitoring of drug manufacturing companies, wholesale, retail, public and private hospital pharmacies and health shops was conducted through Goods Manufacturing Production (GMP) inspections and Good Distribution Practices (GDP) - Post Licensing Inspections. The following was established:

#### **6.1.2.1.1** Good Manufacturing Production Inspections

Good Manufacturing Practice (GMP) plays a major role in the quality management system to ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation. <sup>90</sup> In this regard, ZAMRA conducts GMP inspections on local drug manufacturing companies and where need arises on foreign drug manufacturing companies requiring marketing authorisation.

The audit established that GMP inspections were conducted at least once annually and that inspections were risk based depending on the level of adherence to WHO four (4) critical systems namely documentation, hygiene of premises, utilities, and ventilation. Figure 6.7 below shows the trend of GMP inspections from 2017 to 2021.

<sup>88</sup> ZAMRA Standards of Pharmaceutical Practice.

<sup>89</sup>https://www.adb.org/sites/default/files/publication/184392/better-regulation-medicine.pdf

<sup>&</sup>lt;sup>90</sup>https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/norms-and-standards-for-

 $pharmaceuticals/guidelines/production\#:\sim: text=WHO\%20 good\%20 manufacturing\%20 practices, required\%20 by\%20 the\%20 marketing\%20 authorization.$ 

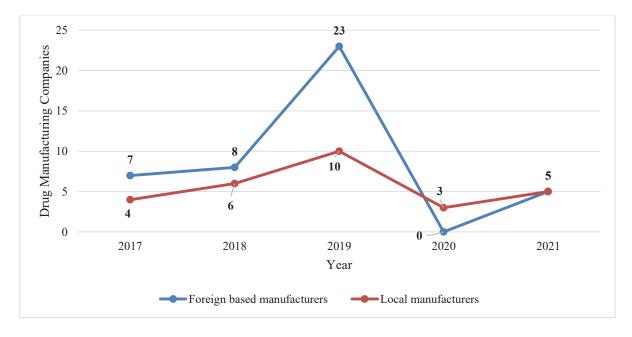


Figure 6.7: Trend of GMP Inspections from 2017 - 2021

Source: ZAMRA Draft Annual Report 2021

From figure 6.7 above, it can be seen that from 2019 to 2020 the number of GMP inspections for both local and foreign drug manufacturing companies reduced significantly from ten (10) to three (3) and twenty-three (23) to zero (0) for local and foreign drug manufacturing companies respectively due to the COVID 19 pandemic. However, from 2020 to 2021, the number of inspections for both drug manufacturing companies increased from three (3) to five (5) and zero (0) to five (5) due to eased COVID 19 travel restrictions by Government.

However, despite ZAMRA having conducted inspections in eleven (11) drug manufacturing companies, the Authority had not fully enforced the GMP guidelines as observed during physical inspections where it was established that three (3) drug manufacturing companies<sup>91</sup>did not fully comply with GMP guidelines. Pharmanova had low compliance while Yash Life Sciences and Mylan Laboratories Limited complied to a greater extent to GMPs. For example, it was noted that Pharmanova did not have artificial ventilation which affected the quality of medicines. Further, human and material entry points were not separated thereby causing a risk of cross contamination, and workers in different departments wore similar Personal Protective Equipment (PPE) causing a risk of cross contamination. It was also observed that production areas were not restricted and there was no labelling of functional areas within the plant causing a risk of cross contamination.

<sup>91</sup> Yash Life Sciences, Mylan Laboratories Limited and Pharmanova Zambia

Failure to strictly enforce compliance of GMP guidelines compromised the quality of medicines being produced thereby posing a risk to public health.

#### 6.1.2.1.2 Good Distribution Practices - Post Licensing Inspections

Good Distribution Practices (GDP) ensure that quality of pharmaceutical products is assured by means of adequate control and securing the distribution system from falsified, unapproved, illegally imported, stolen, sub-standard, adulterated and/or misbranded pharmaceutical products. <sup>92</sup>The audit established that the Authority conducted post licensing inspections through routine and spot checks, alerts from the public or WHO on registered premises. Interviews with ZAMRA officials revealed that although sub regions were supposed to inspect each premise at least once per year, the inspections were not conducted for all the premises. During the period under review, ZAMRA conducted post licensing inspections as shown in table 6.3 below:

Table 6.3: Number of Post Licensing Inspections

No.	Details	2019	2020	2021	2022
1	Retail Pharmacies	275	331	453	Not provided
2	Wholesale Pharmacy	21	79	23	Not provided
3	Health Shops	0	62	49	Not provided
4	Hospital Pharmacies (Public and Private)	3	28	6	Not provided
	Total	299	500	531	

Source: Zambia Medicines Regulatory Authority Database 2022

From table 6.3 above, it can be noted that in comparison with 2019, there was an increase in the number of postlicensing inspections from 299 to 500 representing 59.8% in 2020 while there was a further increase from 500 to 531 representing 6.2% in 2021. As for 2019 to 2020, there was generally a significant increase across all types of establishments. However, in 2020 to 2021, there was a decrease in the number of post licensing inspections for all types of establishments with the exception of retail pharmacies. The decrease was attributed to ZAMRA prioritising the inspection of new premises.

Although the Authority had reported an increase in the number of inspections, physical inspections conducted at 153 premises revealed that sixty (60) out of sixty-two (62) public health facilities were not registered with the Authority, therefore, no inspections were carried out. In addition, the

<sup>92</sup>https://apps.who.int/iris/bitstream/handle/10665/330887/DI332-194-225-eng.pdf

following were observed: two (2) premises were not registered with the Authority but had a post licensing inspection; fifty eight (58) were inspected at least once or more while thirty two (32) had no post licensing inspection carried out from date of registration with the Authority as far back as 2006. **Appendix 10** refers. Table 6.4 below shows registered premises that have not had post licensing inspection.

Table 6.4: Registered Premises that have not had Post Licensing Inspections

No.	Province	District	Premises	Date for Certificate of Registration
1	Lusaka	Lusaka	Five Star Pharmacy	03.11.2014
2	Lusaka	Lusaka	Nimoz Pharmacy	24.08.2018
3	Lusaka	Lusaka	Etiquette A Plus Pharmacy	20.04.2017
4	Lusaka	Lusaka	Ruth Kaluluma Memorial Hospital	15.07.2021
5	Lusaka	Lusaka	Healing Touch Pharmacy	21.12.2021
6	Lusaka	Lusaka	Best Value Pharmacy	23.02.2021
7	Lusaka	Lusaka	Gatbro International Limited (wholesale)	09.06.2011
8	Lusaka	Lusaka	Live Health Pharmacy	25.01.2017
9	Lusaka	Lusaka	Lusaka Health Care	06.03.2019
10	Lusaka	Lusaka	Staywell Pharmacy	2019 but reappiled 22/05/22
11	Lusaka	Lusaka	Karibu Chemist Limited	22.10.2012
12	Lusaka	Lusaka	Mums Care Hospital	19.12.2007
13	Lusaka	Lusaka	Lusaka Trust Hospital	20.02.2006
14	Lusaka	Lusaka	ZAMMSA	22.11.2021
15	Lusaka	Lusaka	Komi Community pharmacy	Not Provided
16	Lusaka	Kafue	Mavlo Pharmacy	22.07.2021
17	Central	Kabwe	Davon health Shop	19.12.2013
18	Central	Chibombo	Big Chamz Health Shop	09.12.2019
19	Central	Chibombo	Spring Pharmacy Limited	24.07.2020
20	Copperbelt	Ndola	Mary Begg Hospital	09.09.2018
21	Copperbelt	Ndola	Mpharma	13.08.2019, 03.03.2020, 21.10.2020
22	Copperbelt	Ndola	Gift Health Shop	Not provided
23	Copperbelt	Ndola	Day Break Pharmacy	26.10.2021
24	Copperbelt	Kitwe	Wusakile Mine Hospital	Not Provided
25	Copperbelt	Ndola	Ndola Teaching Hospital	Not provided

26	Copperbelt	Ndola	Chemopharm Pharmacy	28.08.2019
27	Copperbelt	Mufulira	Bukari Health Shop	Not provided
28	Copperbelt	Mufulira	Liwanzika health Shop	Not provided
29	Copperbelt	Chingola	Better Life Health Shop	Not provided
30	Western	Kaoma	Mamu Pharmacy	03.12.2019
31	Southern	Livingstone	Nico Memorial Clinic	Not provided
32	Southern	Livingstone	Safeway Health Shop	Not provided

Source: OAG Performance Audit Field Data 2022

The reasons for not carrying out post licensing inspections of the registered premiseswere attributed to ZAMRA prioritising the inspection of new registered premises due to low staffing levels. Table 6.5 shows the coverage, available staff and number of premises managed for the three (3) regions. See **Appendix 11** for details.

Table 6.5: Coverage, Available Staff and Number of Premises per Region

No		Coverage		Number of registered
No.	Region	Coverage	Number of inspectors	premises
1	Copperbelt - Ndola	<ul> <li>North Western</li> <li>Northern</li> <li>Muchinga</li> <li>Luapula</li> <li>Parts of Central province</li> <li>Two (2) ports of entry namely Nakonde border and Simon Mwansa Kapwepwe Airport</li> </ul>	8	336
2	Eastern - Chipata	Eastern province	3	54
3	Lusaka	<ul> <li>Lusaka</li> <li>Southern</li> <li>Western province</li> <li>Victoria Falls</li> <li>Harry Mwaanga Nkumbula Airport</li> <li>KatimaMulilo border</li> <li>Kazungula border</li> <li>Chirundu border and Kenneth Kaunda International Airport (KKIA)</li> </ul>	15	892

Source: OAG Performance Audit Field Data 2022

Failure to carry out post licensing inspections on registered premises posed a risk of non-compliance to set pharmaceutical guidelines. Physical inspections carried out at ninety one (91) registered premises in June 2022 revealed the following: non-availability of pharmacists; non-

pharmacy personnel dispensing medicines; ceilings in poor condition; non- updated temperature charts; expired and dangerous drug registers not updated; comingling of vaccines and medicines with food in cold chain premises; and non-availability of Standards of Operating Procedures (SoPs) and mandatory reference materials among others. See **Appendix 12** for detailed field inspection findings on registered premises. Figures 6.8, 6.9 and 6.10 shows pictorial evidence of some anomalies found during the inspections.

Figure 6.8: Stained Ceiling due to Leakages at Five Star Pharmacy in Lusaka

Source: Performance Audit Field Data 2022



Figure 6.9: Vaccines mixed with food and drinks at Lusaka Health Care Pharmacy in Lusaka

Source: Performance Audit Field Data 2022

Kraru 50

Figure 6.10: Medicines Comingled with Allied Substances at Nimoz Pharmacy in Lusaka

Source: Performance Audit Field Data 2022

#### 6.1.2.2 Enforcement

Enforcement plays a key role in ensuring that the regulatory requirements and standards for medicines in the country are adhered to at all times by every individual. According to the MASA, the Authority should establish, maintain and enforce standards relating to the manufacture, importation, exportation, distribution and sale of medicines.<sup>93</sup>

The Authority may order the closure of a pharmacy where; the pharmacy contravenes the terms and conditions of registration or any other relevant law or a pharmacy is not registered under the MASA; The Authority is required to give the pharmacy written notice of the violation of the MASA or its certificate of registration, to which a pharmacy should within fourteen days of service of the notice provide written plan of correction of the violation to the Director-General. Where the plan is rejected by the Director-General, the Authority shall revoke the certificate of registration and order the closure of the pharmacy. <sup>94</sup>

<sup>93</sup> MASA No. 3 of 2013 Part II Section 5 (i)

<sup>&</sup>lt;sup>94</sup>MASA No.3 of 2013 Part III Section 24 (1) – (5)

A review of Annual Reports for the period under review revealed that ZAMRA had established standards relating to manufacture, importation, exportation, distribution and sale of medicines. Enforcement activities were also conducted which included; closure of unregistered premises, seizure of unauthorised medicinal products, issuance of warnings, prosecution of offenders, destination inspections and enhanced control of designated ports of entry for medicines among others. 95

However, a review of seizure forms revealed that twenty-five (25) premises without a certificate of registration stocked assorted authorised medicines which implied that the medicines where procured from a duly registered distributor. This was contrary to the MASA which prohibits wholesaler, manufacturer or importers to sell any medicine to any person unless that person is duly authorised to handle medicines.<sup>96</sup> See **Appendix 13** for details.

This showed a weakness in the system in controlling the sale of medicines to only authorised persons. As a result, there was a risk that non-pharmacy personnel may dispense wrong medicines and incorrect doses to patients as well as the risk of failure to track medicines should there be a recall.

Furthermore, physical inspections revealed that ZAMRAs enforcement was not stringent enough to deter non-compliance as the following was observed:

# i. Closure of Non-Compliant Premises

Physical inspections revealed that Happy Pill, Best Value, Save Life, and Etiquette A Plus Pharmacies in Lusaka; Joy of Life Pharmacy in Kitwe, and Mamu Pharmacy in Kaoma had non – pharmacist personnel operating the premises and dispensing Prescription Only Medicines (POMs). It was also observed that ZAMRA did not have locks to prevent pharmacies from re-opening regulated premises once instructed to close due to noncompliance. Further, a ZAMRA inspector only directed the non-pharmacy personnel to close the premises and requested that the Directors report to ZAMRA Offices before resuming operations. This however did not guarantee non-operation by the business owners who still had access to the premises.

#### ii. Inconsistencies in Seizure of Unauthorised Products

The seizure of unauthorised products was not carried out in uniformity as some ZAMRA inspectors were aware of the requirement to seize medication that did not meet required standards on the market while others were not aware. For example, Care Solution which was an unauthorised product was sold in many pharmacies despite the Authority being aware of its presence on the market. During field inspections in July 2022, inspectors in

- 37 -

<sup>95</sup> ZAMRA Annual Reports 2019 to 2021

<sup>&</sup>lt;sup>96</sup> MASA Section 44(4)

Lusaka seized 250 x 250mls bottles of Care Solution while, in Ndola, it was observed that inspectors did not seize the Care Solution. Upon enquiry, Ndola inspectors revealed lack of awareness that the Solution was unauthorised. However, it was noted that 43 x 250mls bottles were seized during inspections, following the enquiry. Failure to seize unauthorised products may result in the increase in unauthorised medicines in the country which may compromise public health and safety.

#### iii. Failure to Implement Inspectors' Recommendation

As the Authority conducts inspections, action is taken depending on the nature of the non-conformance observed which could be minor, major or critical.

For minor deficiencies which do not pose a risk on the quality of products being stored and can be addressed within time, advise is given on corrective measures. However, should a registered premise fail to address critical deficiencies, invocation of the provisions in the various regulations is done which include: issuance of notices to suspend the licenses, permits or certificates.<sup>97</sup>

A review of the inspectors' book in 61 out of 153 premises revealed that all the premises had at least one (1) post licensing inspection undertaken by the Authority. However, it was established that seven (7) premises namely: Lusaka Pharmaceuticals, Chirundu Pharmacy, Wusakile Mine Hospital in Kitwe, Mazabuka General Hospital, Mylan Pharmaceuticals in Lusaka and Yash Life Sciences in Kafue had fully implemented the Authoritys' recommendations in the inspectors' book at the time of the last post licensing inspection, while fifty-four (54) premises had not fully implemented the inspectors' recommendations as of November 2022. It was further established that 92 out of 153 premises had no inspectors' book as sixty (60) public health facilities were not registered with the Authority and the thirty-two (32) premises did not have a post licensing inspection. **Appendix14** refers.

#### iv. Inadequate Sensitisation

The audit established that the Authority had not emphasised the importance of protecting public health through the control and regulation of medicine and the role of citizens in protecting public health. This was revealed through interviews with officials from ZAMRA who stated that they faced aggression and low co-operation from the public during enforcement activities such as raids on unregistered premises. In this regard, it was reported that in some instances members of the public aided unregistered premises by forewarning them of ZAMRAs impeding enforcement activities. This was evidenced during physical inspections, where a spot check on Glen and Mafable pharmacy in Shikoswe area, Kafue district and Vatika Health Shop in Chibombo district resulted in the targeted premises closing their premises thereby making it difficult for the team to conduct inspections.

<sup>97</sup>ZAMRA interviews

The reason for weak enforcement was attributed to inadequate collaboration with stakeholders, lack of presence countrywide and lack of enforcement tools such as locks and seals. The risk associated with failure to undertake effective enforcement may result in continued operations of unregistered premises and may further encourage non-compliance to good pharmaceutical practices.

#### **6.1.2.3 Post Market Surveillance Activities**

The MASA mandates an inspector at any reasonable time, and on the authority of a warrant, to enter any premises, pharmacy, health shop, container, vessel, vehicle, aircraft or other conveyance that the inspector has reasonable grounds to believe is used for the commission of an offence or purposes contrary to the provisions of this Act and take samples of any medicine as maybe necessary for the purposes of testing, examination or analysis.<sup>98</sup>

Post Marketing Surveillance (PMS) refers to the process of monitoring the safety of drugs on the market. Targeted regular inspections of manufacturers along the supply chain can remove poor quality medicines from the market to address sub-standard and counterfeit health products. <sup>99</sup> The audit established that the Authority had an Annual Sampling Plan of 600 with a quarterly target of 150 samples which outlined the type and number of medicines to be collected for purposes of quality evaluation. The samples were drawn based on public health importance which included: Antiretroviral Therapy(ART); Antimalarial; Tuberculosis; most used essential medicines; most imported medicines and most prone to falsification medicines. During the period under review the following samples were evaluated as seen in Table 6.6 below:

Table 6.6: Sampling Plans 2019 - 2022

No.	Quarters	2019	2020	2021	<b>Jan - June 2022</b>
1	1 <sup>st</sup>	227	78	55	50
2	2 <sup>nd</sup>	6	90	239	84
3	3 <sup>rd</sup>	4	220	263	Not provided
4	4 <sup>th</sup>	4	11	74	Not provided
Annual Total S	amples	241	399	631	134

Source: OAG Performance Audit Analysis 2022

From table 6.6 above, it can be seen that from the annual target of 600 samples, ZAMRA sampled 241 in 2019 representing 40.17%, 399 in 2020 representing 66.5% and 631 in 2021 there by

<sup>98</sup>MASA No 3 of 2013 Part VIII Section 55 (4)(f)

<sup>99</sup>https://www.adb.org/sites/default/files/publication/184392/better-regulation-medicine.pdf

exceeding the target with the percentage of 105% while as at June 2022, 134 were sampled representing 44.7%. An analysis showed that the Authority only achieved sampling targets in 2021 where it exceeded the planned number of samples tested while in 2019 and 2020, targets were not achieved by as much as 59%. The achieved targets in 2021 was attributed to the use of portable mini laboratory tests and an increase in ADRs pertaining to COVID vaccines.

Further, a review of Sampling Registers from 2019 to May 2022 revealed that the PMS Section planned to sample 310 medical products as follows: seventy-six (76) in 2019; seventy-six (76) in 2020; eighty-five (85) in 2021; and 123 in 2022. See **Appendix 15**.

The figure below shows the total planned vs samplescollected between 2019 and May 2022.

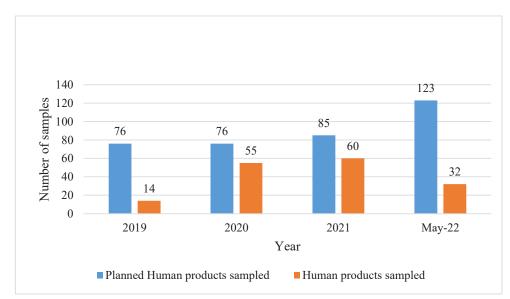


Figure 6.11: Planned versus Samples Collected 2019 - May 2022

Source: OAG Performance Audit Data Analysis 2019 – May 2022

As seen in figure 6.11 above, the Authority did not meet the sampling target as samples tested were lower than planned. From the analysis, it was revealed that fourteen (14) out of seventy-six (76) representing 18.42% in 2019, fifty-five (55) out of seventy-six (76) representing 72.37% in 2020, sixty (60) out of eighty-five (85) representing 70.59% in 2021 and 32 out of 123 representing 26% as at May 2022 were sampled. There was an improvement in the number of samples collected in 2020 in comparison to 2019 with an increase of 74.5% which was attributed to strengthened PMS activities which included the introduction of mini lab kits in regional offices; and increased reporting of product quality defects by healthcare workers as a result of advocacy/sensitisation by the Authority through Pharmacovigilance. In addition, there was pre-distribution screening of Health Centre Kits from ZAMMSA in 2021 that also contributed to an increase in the number of medicines sampled. However, despite the increase in the number of samples collected and tested between 2019 and 2021, the Authority did not meet sampling targets. This may result in substandard or falsified medical products circulating on the market which may have a negative effect on public health.

#### 6.1.2.4 Pharmacovigilance

The Authority shall by statutory instrument, make regulations for monitoring the safety of medicines as well as for the recall or withdrawal of medicines that do not meet the prescribed standards of quality, efficacy and safety. <sup>100</sup>In addition, Marketing Authorisation holders should maintain an appropriate pharmacovigilance system for monitoring, detecting and reporting adverse drug reactions and the performance of products granted MA. <sup>101</sup>

Pharmacovigilance activities are undertaken in order to strengthen monitoring of the safety of medicines through processing reports of suspected medicines quality problems and adverse drug reactions. When a product is confirmed to be defective, an appropriate regulatory action is undertaken, including instituting product recall, undertaking a GMP inspection, and suspension and/or revocation of MA. All health facilities are issued with ADR reporting books which are placed in easily accessible areas such as clinical areas for ART, In-patient, OPD, and TB clinic. Documentary reviews revealed that the Authority established a National Pharmacovigilance Unit (NPU) which was the hub of the pharmacovigilance system. To this effect, ZAMRA developed guidelines for detecting and reporting adverse drug or vaccine reactions and events as well as a hand book for Pharmacovigilance.

Field inspections of health facilities premises confirmed existence of a pharmacovigilance system as inspected health facilities stated the processes followed when an ADR was reported. It was however observed that in public health facilities, the Pharmacovigilance Register was mainly maintained at the ART pharmacy while there were no registers at the main pharmacy. Direct observation during dispensing of medicines at all main pharmacies revealed that there was no sensitisation to patients on the need to report ADRs in the event of an adverse reaction.

A further analysis of the MA Section Annual Reports for the period 2019 to 2021 revealed that NPU had received 7672 ADR reports during the period under review asas follows: 628 in 2019; 2172 in 2020; 2893 in 2021 and 1979 as at June 2022. From the reports received, the Authority processed 640 in 2019, 2137 in 2020, 916 in 2021 and 154 as at November 2022 as shown in the table 6.7 below.

<sup>&</sup>lt;sup>100</sup> MASA No. 13 of 2013 Part IX Section 69(g)

<sup>&</sup>lt;sup>101</sup> Statutory Instruments No.42 Terms and Conditions of the Marketing Authorisation 22nd November, 2019

Table 6.7: Pharmacovigilance Reports Received and Processed

PHARMACOVIGILANCE REPORTS					
Year	2019	2020	2021	Nov-22	Total
Recieved	628	2172	2893	2971	8,664
% increase		245.86	33.20	2.70	
Processed	640	2137	916	154	3,847
		233.91	-57.14	-83.19	
Carried Forward	0	35	1977	2763	4,775

Source: ZAMRA MA Statistics 2019 to 2022

As can be seen in table 6.7 above, there was an increase in the number of pharmacovigilance reports received during the period under review with the percentage increase of 245.86% between 2019 and 2020 and 33.2% between 2020 and 2021 while as at November 2022 there was a 2.7% incease in the number of Pharmacovigilance reports received. In 2021, the Authority only processed 31.7% of Pharmacovigilance reports with the same period accounting for 1977 carried forward reports. Additionally, MA Annual Reports 2019 to 2021 and interviews with officials from ZAMRA revealed that in as much as there was an increase in reporting of ADRs, the number of reports received was low due to low public awareness on the need to report ADRs experienced after consumption of medication. The low number of ADRs reported was also attributed to lack of knowledge or training of staff on reporting and its importance, and low number of staff in the Unit as there were three (3) staff who also carried out Clinical Trials duties. In addition, there was reported high staff turnover of trained staff, staff workload (no time to complete the reporting forms), and lack of tools such as reporting forms and guidance documents. Further, the audit established that the Authority did not provide feedback on Pharmacovigilance Reports which also contributed to reluctance by health facilities to report ADRs.

The audit also established that the Authority recalled a total of thirty-five (35) medicines during the period under review. The recalls were based on alerts from Manufacturers, WHO and ZAMRA Pharmacovigilance Reports. Out the thirty-five (35) recalls, eleven (11) were in 2019, nine (9) in 2020, ten (10) in 2021 and five (5) medicines as at May 2022. See **Appendix 16**.

Delayed processing of Pharmacovigilance Reports poses a risk to public health as medicines that have the potential to cause adverse reactions will continue circulating on the Zambian market.

#### 6.1.2.5 Laboratory Services

The Authority shall establish the NDQCL and shall use the Laboratory to among others; verify the safety, quality and efficacy of medicines which are manufactured or imported into the country by persons who are authorised or licensed under the MASA. The laboratory should ensure that measurement results are traceable to the international system of units through calibration provided by a competent laboratory and certification of values of certified reference material. 103

Laboratory Services play a critical role of sample analysis to provide assurance on the quality, efficacy and safety of medicines thereby safeguarding public health.<sup>104</sup> It is also a source of information on drug resistance, drug monitoring as well as augments regulatory decisions from an informed position<sup>105</sup>. Detailed below are the findings that pertain to laboratory services:

# a) Accreditation of the National Drug Quality Control Laboratory

The benefits of having an International Organisation for Standardisation(ISO) accredited laboratory range from strategic external businessto internal improvement. <sup>106</sup> A few are highlighted below:

#### i. Increasing Customer Confidence

Accreditation to ISO/IEC 17025:2017 demonstrates that a laboratory is capable of providing consistently valid results, that individuals performing the work are competent, and that all accredited measurement results can be traced back to the International System of Units or appropriate references. This is the primary objective for customers, so that results are accepted between countries.

#### ii. Creating a Proactive Risk-Based Business and Quality Culture

Defined activities, policies, and quality objectives are the foundation for the strategic direction of the organisation. A culture of risk-based thinking drives cost-effective operations and evidence-based decision making. The laboratory must plan actions to address risks and drive improvements and ensure that major quality risks related to tests and calibrations are known and controlled.

#### iii. Assuring the Laboratory's Credibility

The test and calibration methods must be reviewed and audited to ensure that the latest technology and documentation are in use. Assessment by a third-party accreditation body verifies that tests and calibrations are done correctly by trained laboratory professionals.

<sup>&</sup>lt;sup>102</sup>MASA No. 3 of 2013 PART VII section 54. (1) (2)

<sup>&</sup>lt;sup>103</sup>International Organisation of Standardisation (ISO) 17025

<sup>&</sup>lt;sup>104</sup>ZAMRA Annual Report 2019

<sup>&</sup>lt;sup>105</sup> Zambia Medicines Regulatory Authority Pharmacovigilance Reference Manual Second Edition March 2020

<sup>106</sup>https://advisera.com/17025academy/what-is-iso-17025/

The audit established that the Authority expressed interest in WHO Prequalification of the NDQCL in October 2021. However, the laboratory was not prequalified as at December 2022. According to the Authority, WHO indicated that the delay to send Auditors to inspect the Laboratory for prequalification was due to the Covid19 travel restrictions which had not been lifted within WHO prequalification unit as at June 2022. Furthermore, it was reported that laboratories in Africa had not been scheduled for Audits in 2022.

The audit also established that the NDQCL was not ISO 17025 accredited as the Authority had not satisfied the necessary requirements such as implementation of a Quality Management System (QMS), internal audits to address non-conformances and risk, competence of personnel and equipment qualification and calibration. Consequently, certain sample types could not be analysed at the NDQCL resulting in outsourcing in the region which attracted considerable costs. Non-accreditation may also expose the laboratory to quality risks, reduced credibility in the region and loss of customer confidence.

#### b) Sample Analysis

A review of ZAMRA Annual Reports 2019 to 2021 revealed that the Authority carried out an analysis of samples from PMS activities for various quality control testing and other regulatory interventions. Table 6.8 below shows the number of samples analysed from 2019 to June 2022.

Received **Processed** C/F 2019 428 358 70 2020 373 291 82 2021 453 670 217 2022 109 84 25 394 **Grand Total** 1580 1186

Table 6.8: Samples Received vs Processed 2019- June 2022

Source: OAG Performance Audit Data Analysis 2022

As can be seen in Table 6.8 above, during the period under review, a total of 1580 samples were received by the laboratory while 1186 were processed representing 75% processing rate with 394 carried forward during the same period.

A review of the ZAMRA Service Charter revealed that the Authority provided for a maximum of twenty-one (21) days for the receipt of duly completed request forms; feedback on requests and issuance of certificates of analysis with a target compliance rate of at least 95%.

The audit further established that lead time between receipt of requests and issuance of certificates of analysis ranged between 30 and 141 days and with the lead time being 141 days in 2019, 89 days in 2020, 51 days in 2021 and reducing to 30 days as of October 2022.

Max lead time Average lead time Difference between maximum Year (days) (days) lead time average lead time 21 141 120 2019 89 2020 21 68 21 51 30 2021 21 30 October 2022

Table 6.9: Lead Time for Sample Analysis 2019 to October 2022

Source: OAG Performance Audit Analysis 2022

The audit also revealed that in as much as the average lead time was reducing, the Authority had not achieved the target rate of 95% compliance. As can be seen in figure 6.12 below, compliance ranged from 7% to 49% during the period under review.



Figure 6.12: Trend of Percentage of Samples Tested within 21 days in 2019 - 2022

Source: OAG Performance Audit Analysis 2022

Failure by the laboratory to process all samples received on a timely basis was attributed to the following:

#### i. Delayed Receipt of Reference Standards and Reagents

To carry out quality sample testing, the NDQCL makes use of reference standards such as the British, United States and International Pharmacopeia. These are primarily purchased in the United States of America, Europe and South Africa. Supply inputs for laboratory operations such as reagents and other accessories are also usually purchased outside the country with a limited supply in-country. It was also established that the Authority did not have Service Contracts with the suppliers of reagents and other accessories which also added

to the delay in receipt of laboratory supplies. According to ZAMRA personnel, clauses in the Service Contracts would provide for continuous and readily available supply of reagents and accessories. Interviews with laboratory personnel also revealed that the leading cause of delays in processing samples and the subsequent issue of certificates of analysis was a long lead time between the requisition and receipt of both reference standards and reagents. It was further established that despite requests for reference standards and reagents being made in good time, the time frame between order and receipt was in some instances as much as 100 days. Delayed receipt of laboratory supplies was also attributed to restrictions in air transport during the COVID 19 pandemic which affected prompt delivery of laboratory inputs.

In response, it was reported that the Authority was in the process of entering into service contracts for various goods and services including the supply of reagents, reference standards and services for service, maintenance and qualification of laboratory equipment.

# ii. Delays in Calibrating Laboratory Equipment

The NDQCL is mandated to provide analytical services to the public in an effective and efficient manner. In order to meet its mandate, the NDQCL is equipped with the state of art testing equipment and instruments.

The equipment and instruments are supposed to be kept in optimal working condition through scheduled performance qualifications and maintenance. This helps to prolong the life of the equipment and to enhance effective operations hence providing confidence in the results generated. The performance qualification and maintenance of the instruments should be done on an annual basis and whenever there is movement of equipment from one location to the other by competent external service providers. The instrument performance verification is also done internally according to the instrument qualification and maintenance schedule.<sup>107</sup>

A review of the equipment qualification and maintenance status reports showed that there were outstanding works on qualification and maintenance of equipment as at October 2022. The audit established that the delays in calibrating the equipment ranged from 35 to 324 days. Further, interviews conducted with officials from ZAMRA revealed that some equipment such as High-Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC1,2,3), High Pressure Liquid Chromatography PerkinElmerALTUS (HPLC4), PerkinElmerALTUS (HPLC4), PerkinElmer Lambda 35 UV/VIS Spectrophotometer (UV-Vis 1), and PerkinElmer Spectrum 100 FTIR Spectrophotometer (FTIR 1) were used for quality testing in unqualified state which may result in inaccurate test results. The audit also established that equipment calibration and qualification was not done annually as prescribed in the Service Charter.

<sup>&</sup>lt;sup>107</sup>Directorate of Laboratory Services Annual Reports 2019 to 2021

The main reason for non-calibration of equipment was attributed to non-availability of internationally competent specialist technicians' in-country to provide the service, as a result, the Authority hired foreign service providers based in South Africa who were not readily available when needed. Furthermore, travel restrictions posed by the COVID 19 virus exacerbated the delay. Delays in calibration and qualification of key equipment may prevent the achievement of set analysis targets which may prevent timely decision making on matters such as recalls, revocation of licenses and prosecutions. See **Appendix 17**.

#### iii. Laboratory Personnel

The audit revealed that the NDQCL had a staff establishment of twenty-six (26) with eleven (11) positions filled while ten (10) positions were in the process of being filled through recruitment as at October 2022. Interviews with officials from ZAMRA and the Laboratory Services Departmental Operations Annual Report 2019 to 2021 revealed that the current staffing was not adequate to meet the demands of a national laboratory. For example, despite the laboratory having the capacity to handle up to 600 samples annually, in 2019, 358 samples were processed, 291 in 2020, 453 in 2021 and 84 as at June 2022.

Failure to provide laboratory services as and when required may result in delays in decision making such as recall of medicine which may impact public health. Furthermore, it may lead to delays in availability of medicines on the market as medicines may remain in quarantine for extended periods until such a time that reagents and reference standards are available to facilitate quality testing.

For example, it was reported that ZAMMSA had on several occasions delayed the distribution of medicines to public health facilities while awaiting certificates of analysis from ZAMRA which in some cases took months to be availed. This may lead to drug shortages in public health facilities which may negatively affect public health.

#### 6.2 Formation of Strategic Alliances with Key Stakeholders

MASA No. 3 of 2013 requires that ZAMRA collaborates with corresponding NMRAs in other countries. According to the ZAMRA Strategic Plan 2019- 2021, one of the Authority's key result areas is improved stakeholder engagement so as to strengthen local and international strategic partnerships. Similarly, the Authority desires to form strong collaborations and partnerships with various stakeholders. 109

<sup>&</sup>lt;sup>108</sup>MASA No. 3 of 2013 Part II, 5 (m)

<sup>&</sup>lt;sup>109</sup> Zambia Medicines Regulatory Authority (ZAMRA) Strategic Plan 2019 - 2021

One of the objectives of the National Health Policy of 2012 is to ensure adequate coordination of roles being played by the many partners in the pharmaceutical industry. Collaboration with national, regional, international and other stakeholder bodies is important as it facilitates the exchange of information and promotion of international best practice. In addition, effective coordination ensures the availability of safe, efficacious, good quality and affordable essential medicines and other medical commodities.

Detailed below are the findings that pertain to the formation of strategic alliances between the Authority and key stakeholders:

# 6.2.1 Sensitisation on Importance of Observing Regulatory Requirements

Sensitisation plays a major role in bringing awareness to the public. The positive effect of sensitisation was seen in the increase in the number of retail pharmacies and health shops registered resulting from mass sensitisation in 2019. A review of the ZAMRA Annual Reports 2019 to 2021 revealed that the Authority carried out sensitisation activities through various platforms such as: production and airing of sensitisation programmes on both print and electronic media; Information, Education and Communication (IEC) materials; Corporate and promotional materials; and sensitisation campaigns. During the period under review, the Authority targeted and sensitised stakeholders namely drug manufacturing companies, wholesalers, importers, exporters, pharmacies, health shops among others on its core mandate.

A review of the Medium-Term Expenditure Framework (MTEF) 2019 to 2022 also revealed that the Authority carried out sensitisation activities that were budgeted and funded in amounts totalling K351,492. See table 6.10.

<sup>&</sup>lt;sup>110</sup> National Health Policy 2012

<sup>&</sup>lt;sup>111</sup> ZAMRA Public Relations Policy 2021

Table 6.10: Public Relations Section Budget vs Funding for Sensitisation Activities 2019 to 2022

No.	Activity (2019 to 2021)	Budget (K)	Funded (K)
1	Conduct community sensitisation in public places in 4 provinces	149,120	149,120
	Activity (2019 to 2021)		
2	Conduct Stakeholder Sensitisation meetings	68,900	68,900
3	Conduct community sensitisation in public places using drama groups/ road shows in 4 provinces (Eastern, Southern, Muchinga and North western Provinces)	133,472	133,472
	Total	351,492	351,492

Source: MTEF 2019 - 2022

In as much as the Public Relations Section was fully funded as seen in table 6.10 above, not all activities were implemented as revealed in the Public Relations Report 2019 to 2021 as detailed below:

#### 6.2.1.1 Planned vs Actual Sensitisation Activities

For the period 2019 to 2022, the Authority planned to conduct a total of 22,157 sensitisation activities of which 22,110 activities were implemented representing 99.8%. The activities included the following: sensitisation activities on both print and electronic media; TV/Radio adverts; adverts and notices; sensitisation campaigns in selected communities using drama performances; participation in public events; stakeholder engagements and IEC materials as shown in **Appendix 18**. In as much as there was a positive achievement, inspections showed that there were still low levels of adherence to pharmaceutical standards from both the general public and pharmacy personnel. This was evidenced from the anomalies that were found in document reviews and during physical inspections. For example, the audit observed that the public purchased: POMs without a prescription; medicines from unregistered premises; and there were premises operating without certificate of registration.

#### **6.2.1.2 Sensitisation Coverage**

The audit established that there was low sensitisation coverage by ZAMRA. This was established through data analysis of the Public Relations Reports 2019 to 2021 which showed that out of the 116 districts in the country, only eight (8) namely; Lusaka, Chipata, Ndola, Kitwe, KapiriMposhi, Livingstone, Kasama and Solwezi were covered for the various categories of sensitisation activities as shown in **Appendix 19**. For example, the sensitisation campaigns using drama performances were only conducted in Lusaka province in two (2) compounds namely Chipata and Garden leaving out other densely populated compounds such as Kanyama, John Howard and Bauleni among others. Media platforms such as radio, print media and television were used as a platform for sensitisation. However, despite countrywide presence of the stated media platforms, it was not possible to ascertain the extent of sensitisation as some locations were outside coverage area while other areas were not on the national grid. Another example was the participation of the Authority in Local and International Exhibitions which was restricted to the Zambia International Trade Fair (ZITF) Exhibition in Ndola and the Zambia Agricultural and Commercial Show in Lusaka to the exclusion of provincial and district agricultural shows.

#### **6.2.1.3 Impact of Sensitisation Activities**

To assess the impact of ZAMRAs sensitisation activities, the Authority relied on feedback through its website, social media (Facebook) and suggestion boxes. They also carried out perception surveys which provided further data on the level of public awareness of ZAMRA's mandate. For example, a customer satisfaction survey conducted by the Authority, in February 2021which targeted the pharmaceutical industry revealed that out of 160 targeted registered premises, only 41 returned the survey form representing 26%. From the returned forms, 67.5% stated that they were knowledgeable about ZAMRAs mandate while 27.5% were fairly knowledgeable and 5% did not indicate their responses on the survey form as shown in figure 6.12.

Figure 6.13: Level of Awareness of ZAMRAs Mandate

Level of Awareness	Percent
Fairly knowledgeable	27.5%
Knowledgeable	67.5%
No response	5.0%

Source: ZAMRA Customer Satisfaction Survey 2021

Despite the survey targeting personnel in the pharmaceutical industry, where it is expected that all pharmaceutical personnel should be aware of the Authoritys' mandate, results showed that there were still personnel who were not aware.

Failure to improve coverage was attributed to low capacity by ZAMRA to enhance sensitisation activities. Interviews with officials from ZAMRA stated that the Public Relations Section had an establishment of two (2) officers with one (1) vacant position of Senior Public Relations Officer as of October 2022. This was coupled with lack of presence of the Authority countrywide which restricted the coverage of public relations activities. This poses a risk of increased number of premises operating illegally as well as the public buying medicines which are not safe, efficacious and of quality.

In response, the Authority stated that they were committed to ensuring that there were continued efforts directed towards promoting and protecting the health of Zambians as manifested through the development and implementation of the 2022 - 2026 Strategic Plan and the planned review of the organisational structure.

#### 6.2.2 Collaboration with Stakeholders

Interviews with ZAMRA officials revealed that they collaborated with Health Professional Council of Zambia (HPCZ), Pharmaceutical Society of Zambia (PSZ) and Zambia Revenue Authority (ZRA) in the control and regulation of medicines in Zambia as detailed below:

# 6.2.2.1 Collaboration with National Medicines Regulatory Authorities

A review of Annual Reports 2019 to 2021 and interviews with officials from ZAMRA revealed that the Authority was a member of ZAZIBONA which is a regional collaboration between NMRAs in Zambia, Zimbabwe, Botswana and Namibia. The aim of the collaboration was to facilitate access to good quality medicines through work-sharing in assessment of products and joint inspection of manufacturing premises. Documentary review of the ZAMRA Annual Reports 2019 to 2021 revealed that the Authority participated in all the ZAZIBONA joint assessment meetings each year. During these meetings, new applications for marketing authorisation and additional information were evaluated, and products were approved or rejected.

# **6.2.2.2** Collaboration with Professional Bodies

The audit established that the Authority collaborated with HPCZ and PSZ. HPCZ interacted with ZAMRA on the basis that ZAMRA was an employer of health professionals such as pharmacists and pharmacy technologists who were regulated by HPCZ. It also undertook joint inspections with ZAMRA when either body received a complaint of a potential illegality around the practice of pharmacy in retail/wholesale sector. HPCZ also stated that they relied on the synergies that they had with ZAMRA and that they benefited from the Authority's inspection of pharmacies.

Further, the audit revealed the Authority placed reliance on the PSZ certification of pharmaceutical personnel which is granted after examination to ensure that only qualified personnel practiced.

#### **6.2.2.3** Collaboration with Local Authorities

The audit established that LAs were a potential key stakeholder in the control and regulation of medicines in the country as they had physical presence in 116 districts in the country. Interviews with ZAMRA and LA officials confirmed that there was no collaboration.

# 6.2.2.4 Collaboration with Zambia Revenue Authority, Drug Enforcement Commission and Zambia Police Service

The audit established, through stakeholder mapping, that ZRA, Drug Enforcement Commission (DEC) and Zambia Police Service (ZPS) were stakeholders in the control and regulation of medicines. It was established that the Authority signed a Memorandum of Understanding (MoU) with Zambia Bureau of Standards (ZABS) and ZRA. In this regard, ZRA facilitated joint inspections with the Authority at ports of entry while DEC inspected dangerous drugs.

ZAMRA further collaborated with DEC to conduct joint raids on unregistered premises with ZPS offering protection. However, it was revealed that there was no written MoU or Service Level Agreements with DEC and ZPS. In response, the Authority stated that they were in the process of formalising their understanding and strengthening collaborations with other regulatory bodies such as HPCZ and the Local Authorities in the regulation of medicines.

Failure to strengthen collaborations between ZAMRA and stakeholders in the control and regulation of medicines was attributed to lack of signed MoUs between the Authority and stakeholders as most of the collaborations were informal and largely voluntary. This may result in weak enforcement which in turn may lead to an increase in unauthorised and sub-standard medicines entering the country.

# **CHAPTER 7: CONCLUSIONS**

The audit concludes that measures are in place to control and regulate medicines. Controls have been developed for the manufacture, storage, importation, distribution and usage of medicines and other recommended good pharmaceutical practices. However, implementation has been weak and not supported by enhanced enforcement for the protection of public health.

Key regulatory processes which include: Marketing Authorisation; Licensing, Surveillance and Enforcement; and quality testing for laboratory services that ensure that quality, safety and efficacy of medicines were in place and pharmaceutical standards were developed by ZAMRA. Implementation of Good Pharmaceutical Practices has been adversely affected by the incapacitation of the Authority in terms of presence in all districts coupled with low manpower which has resulted in low adherence to pharmaceutical standards. Some of the consequences of failure to implement Good Pharmaceutical Practices included: low adherence to pharmaceutical standards by regulated premises; premises operating illegally; unauthorised medicines on the market as well as ineffective quality monitoring of medicines.

Laboratory services are the core of the Authority's operations. Its primary objective is to effectively verify the quality of medicines by carrying out scientific laboratory testing. While the laboratory has developed a number of measures such as QMS, recruitment and training of competent laboratory staff, purchase of modern equipment and making strides towards ISO accreditation, there still remains room for improvement. Staffing continues to be a challenge with the laboratory establishment filled at 42%. This has directly affected the number of samples that can be analysed annually considering that samples processed during the period under review failed to reach the capacity of 600. This is evidenced by the percentage of the samples processed which were between 14% and 75% of the annual capacity. The Authority has not adequately planned and ensured the continuous supply and availability of reagents, accessories and reference standards. The absence of Service Contracts has also contributed to the frequent stock outs that the Authority experiences. This has resulted in long turnaround times which have added to inefficiencies in core business processes. While laboratory equipment may be available, failure to frequently maintain, calibrate and qualify the equipment has exposed the Authority to the risk of producing and disseminating inaccurate test results thereby compromising public health and affecting the credibility of the laboratory.

ZAMRA has ensured strategic stakeholder alliances with HPCZ, PSZ and ZRA but has not created formal collaborations with DEC and ZPS. There is no collaboration with LAs, who have presence in all districts and play a key role in public health. ZAMRA has made strides in sensitising stakeholders'such as drug manufacturing companies, wholesalers, importers, exporters, pharmacies and health shops.

However, public awareness is inadequate as the public continues to purchase medicines from unregistered premises; purchase Prescription Only Medicines (POMs) without a prescription; purchase incomplete dosages of medicines; do not report adverse drug reactions and in some cases, aid and abet illegally operating premises.

# **CHAPTER 8: RECOMMENDATIONS**

This chapeter highlights the OAGs recommended practical improvements on the control and regulation of medicines in Zambia.

From the findings, it is evident that sound and effective regulatory systems are needed to ensure quality, safety and efficacy of medical products and for promotion of public health. Medical products should be highly regulated due to the critical role they play in society and the complexities, and sometimes controversies, associated with assessing their safety, quality, efficacy and effectiveness. As such, it is imperative to have effective and efficient NMRA.

The recommendations, if implemented, may result in reduction in unregistered premises and unauthorised medicines, and improved compliance levels by regulated premises in the country and ultimately enhanced public health.

The audit recommends that ZAMRA should consider:

- developing punitive measures for regulated premises that fail to implement the recommendations provided by the Authority during post licensing inspections in order to ensure that all pharmacies adhere to good pharmaceutical guidelines.
- introducing enforcement tools such as locks. This will ensure non-operation of pharmaceutical premises that have been closed until the matter is resolved and compliance verified.
- reinforcing collaboration and communication with external stakeholders and within the Authority so to enhance enforcement.
- strengthening and building capacity in terms of human resource through collaboration with enforcement agencies in order to enhance the implementation of key regulatory processes given that the Authority has no physical presence in many districts.
- addressing the reasons for the delays in sample processing such as calibration and qualification of equipment, adequate personnel, availability of reference standards and reagents. This can be done by developing Service Contracts and putting in place mechanisms to ensure that reagents and reference standards are readily available by forward planning. This will help to reduce inefficiencies in its core business processes.
- putting in place measures to meet the conditions such as the QMS and competence of staff necessary for ISO accreditation. This will increase the credibility of the laboratory.
- reinforcing sensitisation activities. The Authority should enhance its presence in all districts as well strengthen and build capacity of its staff. This will help to increase awareness to the public and in turn help the Authority in carrying out its mandate.

**Appendix 1:** List of Sampled Premises

No.	Province	District	Facility
		Hos	pital Pharmacy
1	Lusaka	Lusaka	UTH Adult Pharmacy
2	Lusaka	Lusaka	UTH Paediatrics Hospital Pharmacy
3	Lusaka	Lusaka	Levy Mwanawasa Pharmacy
4	Lusaka	Lusaka	Matero L1 Hospital
5	Lusaka	Lusaka	Matero Main Health centre
6	Lusaka	Lusaka	Chipata L1 Hospital
7	Lusaka	Lusaka	Kanyama General Hospital
8	Lusaka	Lusaka	Chawama General Hospital
9	Lusaka	Lusaka	George Health Centre
10	Lusaka	Lusaka	John Howard Health Post
11	Lusaka	Lusaka	Kabwata Health Centre
12	Lusaka	Lusaka	Chilenje Level 1 Hospital
13	Lusaka	Lusaka	State House Urban Health Centre
14	Lusaka	Lusaka	Railway Health Centre
15	Lusaka	Lusaka	Kamwala Health Centre
16	Lusaka	Lusaka	Chelston Zonal Hospital
17	Lusaka	Lusaka	Chainda Health Centre
18	Lusaka	Lusaka	Kalingalinga Health Centre
19	Lusaka	Kafue	Kafue General Hospital
20	Copperbelt	Ndola	Ndola Teaching Hospital
21	Copperbelt	Ndola	Ndeke Mini Hospital
22	Copperbelt	Ndola	Twapia Urban Health Centre
23	Copperbelt	Ndola	Lubuto Clinic
24	Copperbelt	Ndola	Masala Clinic
25	Copperbelt	Ndola	Kawama Clinic
26	Copperbelt	Ndola	Railway surgery Clinic
27	Copperbelt	Ndola	ChipokotaMayamba Clinic
28	Copperbelt	Ndola	Arthur Davison Children's Hospital
29	Copperbelt	Kitwe	Ndeke Mini Hospital

No.	Province	District	Facility
30	Copperbelt	Kitwe	Riverside Clinic
31	Copperbelt	Kitwe	Kwacha Clinic
32	Copperbelt	Kitwe	Buchi Main Clinic
33	Copperbelt	Kitwe	Bulangililo Clinic
34	Copperbelt	Kitwe	Wusakile Mine Hospital
35	Copperbelt	Kitwe	Nkana East Health Centre
36	Copperbelt	Kitwe	Luangwa Urban Health Centre
37	Copperbelt	Kitwe	Mulenga Urban Health Centre
38	Copperbelt	Kitwe	Kitwe Teaching Hospital
39	Copperbelt	Mufulira	Ronald Ross General Hospital
40	Copperbelt	Chingola	Chiwempala Clinic
41	Copperbelt	Chingola	Kabundi East Clinic
42	Central	KapiriMposhi	KapiriMposhi District Hospital
43	Central	KapiriMposhi	Chawama Health Centre
44	Central	KapiriMposhi	TAZARA Clinic
45	Central	Chibombo	Chibombo Rural Health centre
46	Central	Chibombo	Liteta District Hospital
47	Central	Kabwe	Kabwe Central Hospital
48	Central	Kabwe	Mahatma Ghandi Memorial Clinic
49	Southern	Livingstone	Livingstone Teaching Hospital
50	Southern	Chirundu	Mtendere Mission Hospital
51	Southern	Kazungula	Kazungula District Hospital
52	Southern	Mazabuka	Mazabuka General Hospital
53	Western	Mongu	Mongu District Hospital
54	Western	Mongu	Lewanika General Hospital
55	Western	Mongu	Prisons Clinic
56	Western	Senanga	Senanga General Hospital
57	Western	Senanga	Senanga Urban Clinic
58	Western	Kaoma	Kaoma District Hospital
59	Western	Kaoma	Mulamba Urban Clinic
60	Western	Kaoma	Luena Camp Hospital
61	Eastern	Chipata	Walela Health Post
62	Eastern	Katete	Katete General Hospital

No.	Province	District	Facility		
	Private Hospital Pharmacy				
1	Lusaka	Lusaka	Mums Care Hospital		
2	Lusaka	Lusaka	Ruth Kaluluma Memorial Hospital		
3	Lusaka	Lusaka	Lusaka Trust Hospital		
4	Copperbelt	Kitwe	Progress Hospital		
5	Copperbelt	Ndola	Mary Begg Hospital		
6	Southern	Kazungula	Nico Memorial Clinic		
7	Southern	Chirundu	Sebry Clinic		
8	Eastern	Chipata	Altaf Memorial Hospital		
		Ret	ail Pharmacy		
1	Lusaka	Lusaka	Best Value Pharmacy		
2	Lusaka	Lusaka	Downtown Pharmacy		
3	Lusaka	Lusaka	Live Health Pharmacy		
4	Lusaka	Lusaka	Agrimac Pharmacy		
5	Lusaka	Lusaka	Save Life Pharmacy		
6	Lusaka	Lusaka	Southwest Pharmacy		
7	Lusaka	Lusaka	Staywell Pharmacy		
8	Lusaka	Lusaka	Jubilee Chemist		
9	Lusaka	Lusaka	Etiquette A Plus Pharmacy		
10	Lusaka	Lusaka	Five Star Pharmacy		
11	Lusaka	Lusaka	Happy Pill Pharmacy		
12	Lusaka	Lusaka	Karibu Chemist Limited		
13	Lusaka	Lusaka	Komi Community Pharmacy		
14	Lusaka	Lusaka	Lusaka Health Care		
15	Lusaka	Lusaka	We Care Pharmacy		
16	Lusaka	Lusaka	M. Care Pharmacy		
17	Lusaka	Lusaka	Nimoz Pharmacy		
18	Lusaka	Lusaka	Things Pharmacy		
19	Lusaka	Lusaka	Healing Touch Pharmacy Limited		
20	Lusaka	Lusaka	Woodlands Chemist		
21	Lusaka	Lusaka	Neclife Pharmacy		
22	Lusaka	Lusaka	Link Pharmacy		
23	Lusaka	Kafue	Mavlo Pharmacy		

No.	Province	District	Facility
24	Copperbelt	Ndola	Charikam Pharmacy Limited
25	Copperbelt	Ndola	AB Pharmacy
26	Copperbelt	Ndola	Greenshop Pharmacy
27	Copperbelt	Ndola	Karibu Chemist
28	Copperbelt	Ndola	Day break Pharmacy
29	Copperbelt	Ndola	Welvis Pharmacy
30	Copperbelt	Kitwe	Mik Med Pharmacy Limited
31	Copperbelt	Kitwe	Joy of Life Pharmacy
32	Copperbelt	Kitwe	Chimwemwe Medicare Pharmacy Limited
33	Copperbelt	Kitwe	Evergreen Pharmacy
34	Copperbelt	Chingola	Stubbs Chemist
35	Copperbelt	Chingola	Brachi Pharmacy
36	Western	Mongu	Smart Pharmacy Limited
37	Western	Mongu	P & G Health Care
38	Western	Mongu	Premium Care Pharmacy
39	Western	Mongu	Freshview Pharmacy
40	Western	Senanga	Mbuyoti Pharmacy
41	Western	Kaoma	Lesa YeupaBumi Pharmacy
42	Western	Kaoma	Kaoma Pharmacy Limited
43	Western	Kaoma	Joyful Living Pharmacy Limited
44	Western	Kaoma	Mamu Pharmacy
45	Central	Chibombo	Spring Pharmacy Limited
46	Central	Kabwe	Five Star Pharmacy
47	Central	Kabwe	Broken Hill Chemist
48	Central	Kabwe	Kabwe Pharmacy
49	Southern	Kazungula	Medicine World Pharmacy
50	Southern	Kazungula	Bekuchi Pharmacy
51	Southern	Chirundu	Kandende Pharmacy
52	Southern	Chirundu	Chirundu Pharmacy
53	Southern	Livingstone	Livingstone Pharmacy
54	Eastern	Chipata	Chipata Chemist
55	Copperbelt	Ndola	Hosea Chemist Pharmacy
56	Copperbelt	Ndola	Chemopharm Pharmacy

No.	Province	District	Facility		
	Drug Manufacturing Companies				
1	Lusaka	Lusaka	Mylan Pharmaceuticals		
2	Lusaka	Lusaka	Pharmanova Limited		
3	Lusaka	Lusaka	Yash Life Sciences Limited		
		Н	lealthshop		
1	Copperbelt	Ndola	Gift Health Shop		
2	Copperbelt	Ndola	Bukari Health Shop		
3	Copperbelt	Ndola	Mas Health Shop		
4	Copperbelt	Mufulira	Liwanzika Health Shop		
5	Copperbelt	Chingola	Hope Land Health Shop		
6	Copperbelt	Chingola	Better Life Health Shop		
7	Western	Mongu	Seraphim Health Shop		
8	Western	Senanga	Ultimate Health Shop		
9	Central	Chibombo	Big Chamz Health Shop		
10	Central	Chibombo	Medilane Health Shop		
11	Central	Kabwe	Davon Health Shop		
12	Southern	Livingstone	Safeway Health Shop		
13	Southern	Chirundu	Skyline Best Health Care Health Shop		
14	Eastern	Chipata	Gondar Health Shop		
		Whole	esale Pharmacy		
1	Lusaka	Lusaka	ZAMMSA		
2	Lusaka	Lusaka	Lusaka Pharmaceuticals		
3	Lusaka	Lusaka	Gatbro International Limited (wholesale)		
4	Copperbelt	Luanshya	Copperbelt Hub		
5	Copperbelt	Ndola	Ryino Pharmaceuticals		
6	Copperbelt	Ndola	M.Pharma Limited		
7	Copperbelt	Ndola	Ads Pharmaceuticals		
8	Southern	Livingstone	Noor Pharmaceuticals		
9	Western	Mongu	Mongu regional Hub (wholesale)		
10	Lusaka	Lusaka	Lusaka Pharmchem		

Appendix 2a: List of Interviewees – ZAMRA

No.	Regional and Sub Regional Head	Name Of Institution	Position of interviewee	Location
	Copperbelt			
1		ZAMRA Regional and Sub Office	Regulatory Officer	Ndola
			Inspector (Investigations)	
	Southern			
2		ZAMRA Sub Office	Inspector	Livingstone
			A/Inspector	Chirundu
	Lusaka			
3		ZAMRA HQ	Acting Director General	Lusaka
			Acting Director- Medicines Control.	
			Director- Laboratory Services.	
			Head – Physical Chemical Unit (NDQCL)	
			Head – Microbiology(NDQCL)	
			Head Human Resource	
			Internal Auditor	
			Inspector( GMP)	
		KKIA		Lusaka
4	Eastern			
		ZAMRA Regional Office	Principal Regulation Officer	Chipata
			Assistant Inspector	

Appendix 2b: List of Interviewees - Key Stakeholders

No.	Name Of Institution	Position of Interviewee	Location
1	Ministry of Health (MoH)	Director Finance	Lusaka HQ
2	Zambia Development Agency (ZDA)	Acting Director General Legal Counsel	Lusaka HQ
3	Zambia Revenue Authority (ZRA)	Acting Border Head	Kazungula
4	Pharmaceutical Society of Zambia (PSZ)	National Treasurer	Lusaka HQ
5	Health Professional Council of Zambia (HPCZ)	Director–Inspectorate Director-Registration Manager (Inspections and Accreditation) Senior Registration	Lusaka HQ

Appendix 2c: List of Interviewees – Local Authorities

No.	Name of Institution	Position of Interviewee	Location
1	Lusaka City Local Authorities	Director Public health	Lusaka
2	Chibombo Town Local Authorities	Health Inspector	Chibombo
3	Kabwe Town Local Authorities	Director Public Health Chief inspector	Kabwe
4	KapiriMposhi Town Local Authorities	Local Authorities Secretary Deputy Council Secretary Health Inspector District Planning Officer Deputy Treasurer	KapiriMposhi
5	Ndola City Local Authorities	Assistant Director Public Health Chief Inspector	Ndola
6	Kitwe City Local Authorities	Town Clerk	Kitwe
7	Chingola Municipal Local Authorities	Director Public Health	Chingola
8	Kafue Town Local Authorities	Health Inspector Deputy Treasurer	Kafue
9	Chirundu District Local Authorities	Local Authorities Secretary Public Health Inspector Examiner	Chirundu

No.	Name of Institution	Position of Interviewee	Location
10	Kaoma Town Local Authorities	Local Authorities Secretary Senior Health Inspector Health inspector	Kaoma
11	Mongu Town Local Authorities	Public Health Director	Mongu
12	Senanga Town Local Authorities	Health Inspector	Senanga

Appendix 2d: List of Interviewees – Regulated Premises

No.	Name of Institution	Position of Interviewee	Location
1	UTH Adult Pharmacy	Chief Pharmacist	Lusaka
2	UTH Paediatrics. Hospital Pharmacy	Pharmacist	Lusaka
3	Levy Mwanawasa Pharmacy	Pharmacist	Lusaka
4	Matero L1 Hospital	Pharmacist Pharmacist Technologist	Lusaka
5	Matero Main Health centre	Pharmacist Technologist	Lusaka
6	Chipata L1 Hospital	Pharmacist Pharmacist Technologist	Lusaka
7	Kanyama General Hospital	Pharmacist	Lusaka
8	Chawama General Hospital	Pharmacist	Lusaka
9	George Health Centre	Pharmacist	Lusaka
10	John Howard Health Post	Registered Nurse	Lusaka
11	Kabwata Health Centre	Pharmacist	Lusaka
12	Chilenje Level 1 Hospital	Pharmacist	Lusaka
13	State House Urban Health Centre	Pharmacist Technologist	Lusaka
14	Railway Health Centre	Pharmacist	Lusaka
15	Kamwala Health Centre	Pharmacist Technologist	Lusaka
16	Chelston Zonal Hospital	Pharmacist	Lusaka
17	Chainda Health Centre	Pharmacist Technologist	Lusaka
18	Kalingalinga Health Centre	Pharmacist	Lusaka
19	Kafue General Hospital	Pharmacist	Kafue

No.	Name of Institution	Position of Interviewee	Location
20	Ndola Teaching Hospital	Senior Pharmacist	Ndola
21	Ndeke Mini Hospital	Acting Nurse in-charge	Ndola
22	Twapia Urban Health Centre	Pharmacist Technologist	Ndola
23	Lubuto Clinic	Pharmacist Technologist	Ndola
24	Masala clinic	Pharmacist Technologist	Ndola
25	Kawama Clinic	Pharmacist Technologist	Ndola
26	Railway Surgery Clinic	Registered Nurse	Ndola
27	ChipokotaMayamba Clinic	Pharmacist Technologist	Ndola
28	Arthur Davison Children's Hospital	Pharmacist	Ndola
29	Ndeke Mini Hospital	Pharmacist Technologist	Kitwe
30	Riverside Clinic	Registered Nurse	Kitwe
31	Kwacha Clinic	Registered Nurse	Kitwe
32	Buchi Main Clinic	Pharmacist Technologist	Kitwe
33	Bulangililo Clinic	Registered Nurse	Kitwe
34	Wusakile Mine Hospital	Pharmacist	Kitwe
35	Nkana East Health Centre	Registered Nurse	Kitwe
36	Luangwa Urban Health Centre	Pharmacist Technologist	Kitwe
37	Mulenga Urban Health Centre	Pharmacist Technologist	Kitwe
38	Kitwe Teaching hospital	Pharmacist Technologist	Kitwe
39	Ronald Ross General Hospital	Pharmacist	Mufulira
40	Chiwempala Clinic	Pharmacist Technologist	Chingola
41	Kabundi East Clinic	Pharmacist Technologist	Chingola
42	KapiriMposhi District Hospital	Pharmacist Technologist	KapiriMposhi
43	Chawama Health Centre	Registered Nurse	KapiriMposhi
44	TAZARA Clinic	Registered Nurse	KapiriMposhi
45	Chibombo Rural Health centre	Pharmacist Technologist	Chibombo
46	Liteta District Hospital	Pharmacist Technologist	Chibombo
47	Kabwe Central Hospital	Pharmacist	Kabwe
48	Mahatma Ghandi Memorial Clinic	Pharmacist Technologist	Kabwe
49	Livingstone Teaching Hospital	Acting Head of Department (Pharmacy)	Livingstone
50	Mtendere Mission Hospital	Pharmacist	Chirundu
51	Kazungula District Hospital	Medical Doctor in Charge	Kazungula
52	Mazabuka General Hospital	Pharmacist	Mazabuka

No.	Name of Institution	Position of Interviewee	Location
53	Mongu District Hospital	Pharmacist	Mongu
54	Lewanika General Hospital	Pharmacist	Mongu
55	Prisons Clinic	Pharmacist Technologist	Mongu
56	Senanga General Hospital	Pharmacist Technologist	Senanga
57	Senanga Urban Clinic	Registered Nurse	Senanga
58	Kaoma District Hospital	Pharmacist Technologist	Kaoma
59	Mulamba Urban Clinic	Registered Nurse	Kaoma
60	Luena Camp Hospital	Pharmacy Dispenser	Kaoma
61	Walela Health Post	Registered Nurse	Chipata
62	Katete General Hospital	Pharmacist Pharmacist	Katete
02	•	Iospital Pharmacy	Tratete
1	Mums Care Hospital	Pharmacist Technologist	Lusaka
2	Ruth Kaluluma Memorial Hospital	Registered Nurse	Lusaka
3	Lusaka Trust Hospital	Pharmacist	Lusaka
4	Progress Hospital	Pharmacist	Kitwe
5	Mary Begg Hospital	Pharmacist	Ndola
6	Nico Memorial Clinic	Pharmacist	Kazungula
7	Sebry Clinic	Medical Doctor	Chirundu
8	Altaf Memorial Hospital	Pharmacist Technologist	Chipata
	-	nil Pharmacy	Стриш
1		Director	Lusaka
1	Best Value Pharmacy	Pharmacist	
3	Downtown Pharmacy Live Health Pharmacy	Pharmacist	Lusaka Lusaka
4	•	Pharmacist	Lusaka
5	Agrimac Pharmacy Save Life Pharmacy	Buyer	Lusaka
6	Southwest Pharmacy	Pharmacist	Lusaka
7	Staywell Pharmacy	Pharmacist	Lusaka
8	Jubilee Chemist	Pharmacist	Lusaka
9	Etiquette A Plus Pharmacy	Pharmacist	Lusaka
10	Five Star Pharmacy	Pharmacist	Lusaka
11	Happy Pill Pharmacy	Director	Lusaka
12	Karibu Chemist Limited	Pharmacist	Lusaka
13	Komi Community Pharmacy	Pharmacist Technologist	Lusaka
14	Lusaka Health Care	Pharmacist	Lusaka
15	We Care Pharmacy	Pharmacist	Lusaka
16	M. Care Pharmacy	1. Pharmacist	Lusaka

No.	Name of Institution	Position of Interviewee	Location
17	Nimoz Pharmacy	Pharmacist Technologist	Lusaka
18	Things Pharmacy	Pharmacist Technologist	Lusaka
19	Healing Touch Pharmacy Limited	Pharmacist	Lusaka
20	Woodlands Chemist	Pharmacist	Lusaka
21	Neclife Pharmacy	Pharmacist Technologist	Lusaka
22	Link Pharmacy	Pharmacist	Lusaka
23	Mavlo Pharmacy	Pharmacist	Kafue
24	Charikam Pharmacy Limited	Pharmacist	Ndola
25	AB Pharmacy	Pharmacist	Ndola
26	Greenshop Pharmacy	Pharmacist Technologist	Ndola
27	Karibu Chemist	Pharmacist	Ndola
28	Day Break Pharmacy	Pharmacist	Ndola
29	Welvis Pharmacy	Pharmacist	Ndola
30	Mik Med Pharmacy Limited	Sales Lady	Kitwe
31	Joy of Life Pharmacy	COG	Kitwe
32	Chimwemwe Medicare Pharmacy Limited	Pharmacist	Kitwe
33	Evergreen Pharmacy	Pharmacist Technologist	Kitwe
34	Stubbs Chemist	Pharmacist	Chingola
35	Brachi Pharmacy	Pharmacist Technologist	Chingola
36	Smart Pharmacy Limited	Pharmacist Technologist	Mongu
37	P & G Health Care	Pharmacist	Mongu
38	Premium Care Pharmacy	Pharmacist	Mongu
39	Freshview Pharmacy	Clinical Office	Mongu
40	Mbuyoti Pharmacy	Pharmacist Technologist	Senanga
41	Lesa YeupaBumi Pharmacy	Registered Nurse	Kaoma
42	Kaoma Pharmacy Limited	Pharmacist Technologist	Kaoma
43	Joyful Living Pharmacy Limited	Pharmacist	Kaoma
44	Mamu Pharmacy	Chief Executive Officer (CEO)	Kaoma
45	Spring Pharmacy Limited	Pharmacist Technologist	Chibombo
46	Five Star Pharmacy	Pharmacist Technologist	Kabwe
47	Broken Hill Chemist	Pharmacist	Kabwe
48	Kabwe Pharmacy	Pharmacist	Kabwe
49	MedicineWorld Pharmacy	Pharmacist	Kazungula
50	Bekuchi Pharmacy	Pharmacist	Kazungula
51	Kandende Pharmacy	Pharmacist	Chirundu
52	Chirundu Pharmacy	Pharmacist	Chirundu
53	Livingstone Pharmacy	Pharmacist	Livingstone
54	Chipata Chemist	Pharmacist	Chipata

No.	Name of Institution	Position of Interviewee	Location
55	Hosea Chemist Pharmacy	Pharmacist	Ndola
56	Chemopharm Pharmacy	Pharmacist	Ndola
	Medicine Man	nufacturing Companies	
1	Mylan Pharmaceuticals	Pharmacist	Lusaka
2	Pharmanova Limited	Pharmacist	Lusaka
3	Yash Life Sciences Limited	Pharmacist	Lusaka
	Не	ealth Shops	
1	Gift Health Shop	1. Dispenser	Ndola
2	Bukari Health Shop	Pharmacist Technologist	Ndola
3	Mas Health Shop	Helper	Ndola
4	Liwanzika health Shop	Pharmacist Technologist	Mufulira
5	Hope Land Health Shop	Pharmacist Technologist	Chingola
6	Better Life Health Shop	Pharmacist Technologist	Chingola
7	Seraphim Health Shop	Pharmacist Technologist	Mongu
8	Ultimate Health Shop	Dispenser	Senanga
9	Big Chamz Health Shop	Student	Chibombo
10	Medilane Health Shop	Clinical Officer (owner)	Chibombo
11	Davon Health Shop	Assistant Officer	Kabwe
12	Safeway Health Shop	1. Cleaner	Livingstone
13	Skyline Best Health Care Health Shop	Dispenser	Chirundu
14	Gondar Health Shop	Pharmacist Technologist	Chipata
	Whole	esale Pharmacy	
1	ZAMMSA	Pharmacist	Lusaka
2	Lusaka Pharmaceuticals	Pharmacist Technologist	Lusaka
3	Gatbro International Limited (Wholesale)	Pharmacist	Lusaka
4	Copperbelt Hub	Pharmacist Technologist	Luanshya
5	Ryino Pharmaceuticals	Finance Manager	Ndola
6	M.Pharma Limited	1. Warehouse Manager	Ndola
7	Ads Pharmaceuticals	Pharmacist	Ndola
8	Noor Pharmaceuticals	Pharmacist	Livingstone
9	Mongu Regional Hub (Wholesale)	Pharmacist	Mongu
10	Lusaka Pharmchem	Pharmacist	Lusaka

Appendix 3: List of Documents Reviewed

Document and other relevant information required	Purpose of review
Medicines and Allied Substances Act (No.3) of 2013.	To obtain criteria on the legal framework governing and operations of ZAMRA.
Statutory Instruments (SI) SI No.10 of 2016 Agro-Veterinary Shop Permit Regulations SI No.11 of 2016 Dispensing Certificate Regulations SI No.12 of 2016 Health Shop Regulations SI No.38 of 2016 Fees Regulations SI No. 57 of 2017 Importation and Exportation Regulations SI No. 58 of 2017 Certificate of Registration SI No. 79 of 2019 The Medicines and Allied Substance Regulations	To obtain criteria on the regulations governing the operations of ZAMRA.
Seventh National Development Plan (7NDP)2017-2021	To obtain criteria on strategies that government has regarding control and regulation of medicines.
Dangerous Drugs ACT 1994	To check the alignment regarding the legal framework governing the health sector with the MASA.
ZAMRA Strategic Plan (2020-2021)	To obtain targets of the planned activities.
ZAMRA Medium Term Expenditure Framework (MTEF) 2019-2022	To obtain funding and expenditure for ZAMRA for the period under review.
ZAMRA Annual Reports2019 -2022	To obtain trend analysis on the general performance of ZAMRA and obtain information on challenges faced.

Appendix 4: Court Cases on Importation of Medicines Without an Import Permit

No.	Case number	Case type	Court
01	1SPA/029/19	Importing medicines without permit	Lusaka Magistrate Court
02	1PE/100/19	Importing medicines without import permit (Benylin with codeine)	Lusaka Magistrate Court
03	2SPA-093/19	Importing medicines without import permit	Lusaka Magistrate Court
04	SI/116/19	Two counts of importing medicines without permit and failure to maintain records 4/09/19	Livingstone Magistrate Court
05	2A2- 64/2019	Importing medicines without the import permit (Benylin with Codeine)	Kafue Magistrate Court
06	SI/116/2019	Importing medicines without import permit	Livingstone Magistrate Court
07	2SPH/071/2021	Importing medicines without import permit	Lusaka Magistrate Court

Appendix 5: List of Registered Wholesale Pharmacies and Drug Manufacturing Companies

	Wholesale	Pharmacies
No.	Name of Company Pharmaceutical	Physical Address
1	Missionpharma Zambia Limited	Plot No. 35296, Mwembeshi Road, Heavy Industrial Area, Po Box 39303, Lusaka
2	Yash Pharmaceuticals Limited	Lilayi Road, Po Box 34562, Lusaka
3	NRB Pharma Zambia Limited	Of Lusaka Multi-Facility Economic Zone Plot No. Plot No. 22967m, Chifwema Road, Off- Leopard Hill Road
4	International Drug Company Limited	Plot No. 2419, Freedom Way, Lusaka
5	International Drug Company Limited	Plot No. 363/364/477, Industrial Area, Kabwe
6	Yash Life Sciences Limited	Plot No. Plot No. 72503/D, Farm No. 3370, Shimabala, Kafue
7	Kingphar Company Zambia Limited	Plot No. Zccz, Lusaka East Multi-Facility Economic Zone, Lusaka, Zambia
8	Baxy Pharmaceuticals Manufacturing Company Limited	Plot No. 5152,5153, Zambia Road, Po Box 70286, Ndola, Zambia
9	Pharmanova Zambia Limited	Plot No. 7329, Moobola Road, Po Box 31458, Lusaka, Zambia
10	Mylan Laboratories Limited	Plot No. P1/6 Of F10723, Lusaka South Multi- Facility Economic Zone, Lusaka, Zambia
11	Zambia National Blood Transfusion Service – Lusaka Provincial Centre	Lusaka Provincial Centre, University Teaching Hospital Provincial Blood Transfusion Centre, University Teaching Hospital Grounds, Nationalist Road, Ridgeway Area, P/B Rw1x, Lusaka, Zambia

	Drug Manufacturing Companies
1	Missionpharma Zambia Limited, Plot No. 35296, Mwembeshi Road, Heavy Industrial Area, Po Box 39303, Lusaka
2	Yash Pharmaceuticals Limited, Plot No. 27, Lilayi Road, Po Box 34562, Lusaka
3	Nrb Pharma Zambia Limited, Of Lusaka Multi-Facility Economic Zone Plot No. Plot No. 22967m, Chifwema Road, Off-Leopard Hill Road, Lusaka
4	International Drug Company Limited, Plot No. 2419, Freedom Way, Lusaka
5	International Drug Company Limited, Plot No. 363/364/477, Industrial Area, Kabwe

6	Yash Life Sciences Limited, Plot No. Plot No. 72503/D, Farm No. 3370, Shimabala, Kafue
	Drug Manufacturing Companies
7	Kingphar Company Zambia Limited, Plot No. Plot No. Zccz, Lusaka East Multi-Facility Economic Zone, Lusaka, Zambia
8	Baxy Pharmaceuticals Manufacturing Company Limited, Plot No. 5152,5153, Zambia Road, Po Box 70286, Ndola, Zambia
9	Pharmanova Zambia Limited, Plot No. 7329, Moobola Road, Po Box 31458, Lusaka, Zambia
10	Mylan Laboratories Limited, Plot No. P1/6 Of F10723, Lusaka South Multi-Facility Economic Zone, Lusaka, Zambia
11	Zambia National Blood Transfusion Service – Lusaka Provincial Centre, University Teaching Hospital Provincial Blood Transfusion Centre, University Teaching Hospital Grounds, Nationalist Road, Ridgeway Area, P/B Rw1x, Lusaka, Zambia

Appendix 6: List of Local Authorities that submitted list of facilities operating in their Jurisdiction.

No.	District
1	Mongu
2	Shangombo
3	Senanga
4	Kaoma
5	Kafue
6	Chongwe
7	Mazabuka
8	Chinsali
9	Kabwe
10	Kapiri-Mposhi
11	Chibombo
12	Mumbwa
13	Chipangali
14	Nyimba
15	Lumezi
16	Sinda
17	Chadiza
18	Kitwe
19	Ndola
20	Kalumbila
21	Chingola
22	Chirundu

Appendix 7: List of Premises Registered/Unregistered with Local Authorities and ZAMRA

No.	Pharmacy	Address	Province	<b>ZAMRA</b> Registration	Location	Local Authority Registration
П	Mongu Care Pharmacy Limited	Plot No. 55221, Along Independence Avenue, Mongu	Western	Yes	Mongu	Yes
2	P & G Pharmacy Limited	Plot No. 133, Independence Avenue, Mongu	Western	Yes	Mongu	Yes
3	Smart Pharmacy Limited	Independence Avenue, Mongu	Western	Yes	Mongu	Yes
4	Friday I Lilalambowe	Kapulanga	Western	No	Mongu	No
5	Good Grace	Kapulanga	Western	No	Mongu	No
9	New Cosmetic	Independence Avenue, Mongu	Western	No	Mongu	No
7	Premium Care Pharmacy	Stand No. 96, Hass Fuelling Station, Independence Avenue, P.O. Box 910106, Mongu	Western	Yes	Mongu	Yes
∞	Mongu Health	Main Bus Station	Western	No	Mongu	No
6	Femmy Pharmacy	Main Bus Station	Western	No	Mongu	No
10	Pavilion Pharmacy	Along Lewanika Road	Western	No	Mongu	No
11	Vinny Drug Store	Main Bus Station	Western	No	Mongu	No
12	Comfort Pharmacy	Chisonga	Western	No	Mongu	No
13	Life Pharmacy	Barotse Mall	Western	No	Mongu	No
14	Dynalab International Health Shop	Independence Avenue, Mongu	Western	No	Mongu	No
15	Shang City Better Life Health Shop	Shangombo Main Market	Western	No	Shangombo	No
16	Mwamakoi Health Shop	Shangombo Main Market	Western	No	Shangombo	No
17	Seraphim Health Shop	Kaprive Market Area, Along Senanga/ Mongu Road, Senanga	Western	Yes	Senanga	Yes

No.	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration
18	Mbuyoti Pharmacy	Town Centre	Western	No	Senanga	Yes
19	Woodyard Health Shop	Old Market	Western	No	Senanga	No
20	Royal Life Health Shop	Old Market	Western	No	Senanga	No
21	Ultimate Health Shop	Not Provided	Western	No	Senanga	Yes
22	Trust Care Pharmacy	Plot No. 492, Along Hospital Road, Kaoma	Western	Yes	Kaoma	Yes
23	P & G Health Care	Shop No. 2, Freedom Way, Kavindama Complex, Kaoma	Western	Yes	Kaoma	Yes
24	Lesa Yeupa Pharmacy	Plot No. 1762, Zesco Road, Kaoma	Western	Yes	Kaoma	Yes
25	Joyful Living Pharmacy	Plot No. 517, Freedom Way, Kaoma	Western	Yes	Kaoma	Yes
26	Kaoma Pharmacy	Shop No. 194, Kalukungu Area, Kaoma	Western	Yes	Kaoma	Yes
27	Mamu Pharmacy	Kalukungu Market, P.O. Box 940194, Kaoma	Western	Yes	Kaoma	Yes
28	Community 7 Drug Store	Community 7	Lusaka	No	Kafue	No
29	Glacam Pharmacy	Kafue Cbd	Lusaka	No	Kafue	Yes
30	Glen Pharmacy	Stand No. 557/25, Shikoswe Site And Service, Kafue	Lusaka	Yes	Kafue	Yes
31	Healthcheck Pharmacy	Plot No. 5-51/25, Kajima Road, Kafue	Lusaka	Yes	Kafue	Yes
32	Juflona Clinic	Kafue East	Lusaka	No	Kafue	Yes
33	Kafue Drugstore	Kafue Estates C5	Lusaka	No	Kafue	No
34	Kafue Pharmacy	Plot No. 48/09, Kafue Estate, Luangwa Drive, Kafue	Lusaka	Yes	Kafue	Yes
35	Mafable Pharmacy	Shikoswe	Lusaka	No	Kafue	Yes

No.	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration
36	Majolu Health Care Enterprise	Kalukungu Market, Zambia Compound, Kafue	Lusaka	Yes	Kafue	Yes
37	Mavlo Pharmacy	Plot No. 3, Buyantanshi Road, Kafue	Lusaka	Yes	Kafue	Yes
38	Mujy Pharmacy	Kailos Shopping Center, Shantumbu Market, Shantumbu Road, Kafue	Lusaka	Yes	Kafue	Yes
39	Munas Drugstore	Shikoswe	Lusaka	No	Kafue	No
40	Pharmacy Direct	Kafue Cbd	Lusaka	No	Kafue	Yes
41	Smart Life Pharmacy	Kafue Cbd	Lusaka	No	Kafue	Yes
42	Thabo Pharmacy Limited	Shop No. 53, Kafue Road, Kafue	Lusaka	Yes	Kafue	Yes
43	The Things Pharmacy	Shikoswe	Lusaka	No	Kafue	Yes
44	Toriam Pharmacy	Kafue (Chalala)	Lusaka	No	Kafue	Yes
45	Valley Hills Health Care	Plot No. 001, Shop No. 5, Rako Shopping Complex, Off Kafue Road, Kafue	Lusaka	Yes	Kafue	Yes
46	Zubeda Clinic	Nangonwe	Lusaka	No	Kafue	Yes
47	Mother's Legacy Pharmacy	Not provided	Lusaka	No	Chongwe	Yes
48	Chalimbana Drug Store	Not provided	Lusaka	No		Yes
49	Dk Pharmacy	Not provided	Lusaka	No	Chongwe	Yes
50	East Road Pharmacy	Not provided	Lusaka	No	Chongwe	Yes
51	El Health Shop	Not provided	Lusaka	No	Chongwe	Yes
52	Five Star Pharmacies	Plot No. 338, Great East Road, Chongwe	Lusaka	Yes	Chongwe	Yes
53	Fremuya Drug Store	Not provided	Lusaka	No		Yes
54	Genra Pharmaceutical	Not Provided	Lusaka	No	Chongwe	Yes

Š.	Pharmacy	Address	Province	ZAMRA	Location	Local Authority
55	H and E Life Care	Not Provided	Lusaka	No	Chongwe	Yes
56	Lela Pharmacy	Shop No. 2, Off Great East Road, Kakubo Village, Chongwe, Lusaka	Lusaka	Yes	Chongwe	Yes
57	M Care Pharmacy	Waterfalls Service Station, Chongwe	Lusaka	Yes	Chongwe	Yes
58	Mahoweh Pharmacy	Not provided	Lusaka	No	Chongwe	Yes
59	Medex Pharmacy	Shop No.5, Obama Plaza, Obama, Chongwe	Lusaka	Yes	Chongwe	Yes
09	Multicure Pharmacy	Green Roof Complex, Great East Road, Chongwe	Lusaka	Yes	Chongwe	Yes
61	Mungoni Health Care	Not Provided	Lusaka	No	Chongwe	Yes
62	Nesheka Drug Store	Not Provided	Lusaka	No		Yes
63	Ngonga Pharmacy	Not Provided	Lusaka	No	Chongwe	Yes
64	Noah Chilala Drug Store	Not provided	Lusaka	No	Chongwe	Yes
65	Perthville Pharmacy Limited	Plot No. 10, Off Ngwerere Road, Chongwe	Lusaka	Yes	Chongwe	Yes
99	Ronhill Pharmacy	Plot No. 1728/M, Shop No. 3, Ibex Hill, Lusaka	Lusaka	Yes	Chongwe	Yes
<i>L</i> 9	Rosie Health Hub Pharmacy Limited	Plot No. 127, Shop No. 7, Ngwerere Road, Chongwe	Lusaka	Yes	Chongwe	Yes
89	Salutem Pharmacy Limited	Stand No. 1848790, Shop No. 2, Chongwe Shopping Mall, Great East Road, Chongwe	Lusaka	Yes	Chongwe	Yes
69	Sigma Pharmacy	Not Provided	Lusaka	No	Chongwe	Yes
70	Silverest Pharmacy Limited	Plot No. 26443/M, Great East Road, Chongwe	Lusaka	Yes	Chongwe	Yes
71	Tabo Natural Health Centre	Not Provided	Lusaka	No	Chongwe	Yes
72	The 4 Girls Health Shop	Not provided	Lusaka	No	Chongwe	Yes

No.	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration
73	Three Joker Pharmacy	Plot No. 706, Great East Road, Chongwe	Lusaka	Yes	Chongwe	Yes
74	Titanic Pharmacy	Not provided	Lusaka	No	Chongwe	Yes
75	Uninath Health Shop	Not provided	Lusaka	No	Chongwe	Yes
92	Vaitoz Chemist Limited	Plot No. 11846, Lubuko Village, Great East Road, Chongwe	Lusaka	Yes	Chongwe	Yes
77	Veroan Health Shop	Not Provided	Lusaka	No	Chongwe	Yes
78	Well Med Pharmacy	Not Provided	Lusaka	No	Chongwe	Yes
79	Fine Health Pharmacy	Plot No. 9 ,Ndeke Road, Nakambala Extension, Mazabuka	Southern	Yes	Mazabuka	Yes
80	Diva Chemist Limited	Plot No. 19, Livingstone Road, Town Centre	Southern	Yes	Mazabuka	Yes
81	Medcity Pharmacy	Plot No.826, Livingstone Road, Town Centre	Southern	Yes	Mazabuka	Yes
82	Health And Glow Pharmacy	Shop No.8 Main Road, Opposite Shoprite	Southern	Yes	Mazabuka	Yes
83	Little Rock Pharmacy	Shop No.4 Butchers Yard, Livingstone Road	Southern	Yes	Mazabuka	Yes
84	Wonganichem Dispensing Chemist	Livingstone Road, Town Centre	Southern	No	Mazabuka	No
85	Vk Original Drug Store	Kabobola Market	Southern	No	Mazabuka	No
98	BlanchoTradings	Kabobola Market	Southern	No	Mazabuka	No
87	Shinel Health Care	Kabobola Market	Southern	No	Mazabuka	No
88	Chrissy Kays	Kabobola Market	Southern	No	Mazabuka	No
68	EnestHanimbo Drug Store	Kabobola Market	Southern	No	Mazabuka	No
06	Testimony Trading Drug Store	Nakambala Community Market	Southern	No	Mazabuka	No
91	Poline Mate Drug Store	Nakambala Community Market	Southern	No	Mazabuka	No

No.	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration
92	Julien Madichi Drug Store	Nakambala Community Market	Southern	No	Mazabuka	No
93	Mulenga's Drug Store	Nakambala Community Market	Southern	No	Mazabuka	No
94	Charity Chulu Drug Store	Nakambala Community Market	Southern	No	Mazabuka	No
95	Lillian Muchanga Drug Store	Nakambala Community Market	Southern	No	Mazabuka	No
96	Saphagrama Pharmacy	Plot No.2142 Chinsali Town Centre	Muchinga	Yes	Chinsali	Yes
26	Lubuto Pharmacy	Plot No.193 Chinsali Town Centre	Muchinga	Yes	Chinsali	Yes
86	Sigma Investments Limited	Plot No. 72, Freedom Way, Kabwe	Central	Yes	Kabwe	Yes
66	Medpharm Pharmacy	Plot No.847, Katebe Chilufya Street, Kabwe	Central	Yes	Kabwe	Yes
100	Galaxy Pharmacy Limited	Plot No. 63a, Independence Way, Kabwe	Central	Yes	Kabwe	Yes
101	Broken Hill Chemist Limited	Plot No. 82b, Shop No. 2, Independence Way, Kabwe	Central	Yes	Kabwe	Yes
102	Kabwe Pharmacy Limited	Plot No. 68, Buntungwa Street, Kabwe	Central	Yes	Kabwe	Yes
103	Zen Pharmacy Limited	Plot No. 3520/21, Shop No. 20, New Kabwe Mall, Kabwe	Central	Yes	Kabwe	Yes
104	Mukowa Pharmacy	Plot No. 2373, Town Centre, KapiriMposhi	Central	Yes	KapiriMposhi	Yes
105	Home Basics Pharmacy	Plot No. 12869, Great North Road, Chibombo	Central	Yes	Chibombo	Yes
106	Fivestar Pharmacies Limited	Plot No. 3520/21, Great North Road, Kabwe	Central	Yes	Kabwe	Yes
107	Healthcure Pharmacy Limited	Coronation Park Mall, Freedom Way, Kabwe	Central	Yes	Kabwe	Yes
108	C.M Passion Pharmacy Limited	Plot No. 1212,15 Miles Off Great North Road, Chibombo	Central	Yes	Chibombo	Yes
109	Mist Pharmacy	Shop No. S43/B, Great North Road, 15 Miles, Chibombo	Central	Yes	Chibombo	Yes

No.	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration
110	Osasi Pharmacy Limited	Plot No. 9, Great North Road, KapiriMposhi	Central	Yes	KapiriMposhi	Yes
111	Neighbours Pharmacy Limited	Plot No. Fw 469, Great North Road, Chibombo, Central Province	Central	Yes	Chibombo	Yes
112	Health Hub Pharmacy Limited	Shop No. 2, Cbd, Katebe Chilufya Road, Kabwe	Central	Yes	Kabwe	Yes
113	Your Pharmacy Limited	Stand No. 3011, Bwacha Road, Po Box 80281, Kabwe	Central	Yes	Kabwe	Yes
114	Freshpoint Pharmacy	Zanimuone West Next To Royal Medical University, Off Great North Road, Po Box 37486, Chibombo	Central	Yes	Chibombo	Yes
115	Chataika Pharmacy Limited	Plot No. 74, Ipusukilo Road, KapiriMposhi	Central	Yes	KapiriMposhi	Yes
116	Edu Z Pharmacy	10 Miles	Central	No	Chibombo	No
117	Vital Signs Pharmacy	Zani Moune East	Central	No	Chibombo	No
118	Afyacare Pharmacy	Plot No. 12869, Great North Road, Kabangwe, Chibombo	Central	Yes	Chibombo	Yes
119	Wako Investments Limited	Plot No. 635, Town Centre, Freedomway, Kabwe	Central	Yes	Kabwe	Yes
120	Yumbemwicho Care Pharmacy	Plot No. 7232, Chazanga – Kabanana Road, Chibombo	Central	Yes	Chibombo	Yes
121	Osworth Pharmacy	Shamulu Shopping Centre, Selengwe Village, Great North Road, 10 Miles, Chibombo	Central	Yes	Chibombo	Yes
122	Centralmed Pharmacy Limited	Plot No. 692, Independence Avenue, Kabwe	Central	Yes	Kabwe	Yes
123	Elanders Pharmacy	KapiriMposhi Market, Along Ipusukilo Road, KapiriMposhi	Central	Yes	KapiriMposhi	Yes
124	Myne Pharmacy Limited	Plot No. 7004, Mine Kasanda Market, Kabwe	Central	Yes	Kabwe	Yes

No.	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration
140	Clarita Pharmacy	Shop No. 8, Makali Plaza, 13 Miles, Great North Road, Chibombo	Central	Yes	Chibombo	Yes
141	Jeabi Pharmacy Limited	Shop No. 3, Chavuma Street, Off Munkoyo Street, Kabwe	Central	Yes	Kabwe	Yes
142	Triple M Pharmacy	Plot No. 2, Riverside Market, KapiriMposhi	Central	Yes	KapiriMposhi	Yes
143	Makululu Pharmacy	Plot No. 13036, Chiwala Road, Makululu, Kabwe	Central	Yes	Kabwe	Yes
144	Tasa Pharmacy	Plot No. 10652, Kasanda Mine Area, Kabwe	Central	Yes	Kabwe	Yes
145	Edicare Pharmacy	Plot No. 12750/M, Along Mumbwa Road, Situmbeko, Chibombo	Central	Yes	Chibombo	Yes
146	Promise Pharmacy	Kabangwe West	Central	No	Chibombo	No
147	Smartlife Chemist	Plot No. 09. Great North Road, KapiriMphoshi	Central	Yes	KapiriMposhi	Yes
148	Pharmlife Pharmacy Limited	Plot No. 3805, Great North Road, Chibombo	Central	Yes	Chibombo	Yes
149	Central Farmers Nest Pharmacy	Kabwe Mall, Great North Road, Kabwe	Central	Yes	Kabwe	Yes
150	Eureka Pharmacy	Plot No. 8077, Great North Road, 13 Miles, Chibombo	Central	Yes	Chibombo	Yes
151	Preme Life Pharmacy	6 Miles	Central	No	Chibombo	Yes
152	Foundation Care Pharmacy	Shop No. 5, Shifwankula Road, Off Great North Road, Shifwankula Village, Chibombo	Central	Yes	Chibombo	Yes
153	KedodeshaRedosa Health Shop	Mwayasunka	Central	No	Chibombo	No
154	Temumon Enterprise Health Shop	Mwayasunka	Central	No	Chibombo	No
155	ChisiHeaalth Shop	Mwayasunka	Central	No	Chibombo	No
156	Sopria Life Health Shop	Mwachisompola	Central	No	Chibombo	No

Local Authority Registration	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes
Location	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	Chibombo	KapiriMposhi
ZAMRA Registration	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes
Province	Central	Central	Central	Central	Central	Central	Central	Central	Central	Central	Central	Central	Central	Central	Central	Central	Central	Central
Address	Mwachisompola	Mwachisompola	10 Miles	6 Miles	Kabangwe West	Mwachisompola	Chiyuni	Chitanda	15 Miles	Chibombo Turnoff	Chibombo Turnoff	Chibombo Turnoff	Chibombo Turnoff	Plot No. 9, Mumbwa Road, Off Great North Road, Keembe, Chibombo	Plot No 3, Great North Road, Chibombo	Old Mumbwa Road, Chilikwela Village, Chibombo	John Chinena, Great North Road, Chibombo	Shop No 3, Mpunde Market-Ngabwe Road, Kapirimposhi
Pharmacy	Up Liftibg Health Shop	Mwachisompola Health Shop	Med Base Health Shop	Life Plug Health Shop	Jam Merecare Health Shop	Super Klin Enterprise Health Shop	Chiyuni Health Shop	Mart Health And Cosmetics Services	Walurida Health Services	Chibombo Health Shop	Big Chamz Health Shop	Vatika Street Health Shop	Midland Health Shop	Bascreen Health Shop,	Liteta Health Shop,	Myrrah Health Enterprise,	Vmart Health & Cosmetics Services H/Shop	Divine Health Shop,
O N	157	158	159	160	161	162	163	164	165	166	167	168	169	170	171	172	173	174

173         Dung Thunders Health Stop, Roy of Action Complex, Rapin/Mosali         Central         Yes         Kapin/Mosali         Yes           174         Hopevine Health Shop, Raing Georges Street, Rapin/Mosali         Kamilanbow Village, Olf Mumbows and Mumbows	No.	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration	
hop,         Kamilambo Village, Off Mumbwa Road,         Central         Yes         Mumbwa           Rabwe         Rabwe         Central         Yes         Kabwe           th Shop         Shop No. 29, Kachulu Market, Kachulu         Central         Yes         Kabwe           hop,         Great North Road, Chibombo         Central         Yes         Chibombo           y,         Shop No. 2 Zaf Mess Market, Mumbwa         Central         Yes         Mumbwa           p, Limited,         Rapirimposhi         Central         Yes         Kapiri Mposhi           p, Limited,         Rapirimposhi         Central         Yes         Kapiri Mposhi           p, Limited,         Rapirimposhi         Central         Yes         Kapiri Mposhi           kapirimposhi         Central         Yes         Kapiri Mposhi           re         Kapirimposhi         No         Chipangali           re         MadziAtuwa Trading Centre         E		Dung Thunders Healthcare Shop,		Central	Yes	KapiriMposhi	Yes	
th Shop Street, Kabwe Street, Central Yes Kabwe Kabwe Street, Kabwe Street, Kabwe Great North Road, Chibombo Central Yes Chibombo Cop. 2 Jef Mess Market, Mumbwa Central Yes Mumbwa Mumbwa Central Yes Mumbwa Mumbwa Central Yes Kapiri Mposhi Central Yes Kapiri Mposhi Central Sapiringoshi Central Sapiringoshi Central Sapiringoshi Central Sapiringoshi Central Sapiringoshi Central Sapiringoshi Centra Eastern No Chipangali Dre Chipangali Trading Centre Eastern No Chipangali Centre Eastern No Chipangali Centre Eastern No No Nyimba Saronabi Complex, Great East Road Eastern No Nyimba Saronabi Complex, Great East Road Eastern No No Nyimba Centre Eastern No No Nyimba Centre Eastern No No Nyimba Saronabi Complex, Great East Road Eastern No No Nyimba Hot No. 62, Lumezi Trading Center Eastern No Lumezi Plot No. 63, Lumezi Trading Area Eastern No Lumezi Plot No. 63, Lumezi Trading Area Eastern No Lumezi Sinda		Hopevine Health Shop,	Kamilambo Village, Off Mumbwa Road, Mumbwa	Central	Yes	Mumbwa	Yes	
hop         Shop No. 29, Kachulu Market, Kachulu Market, Kachulu Market, Kachulu Market, Kachulu Market, Kachulu Market, Kabwe         Central         Yes         Kabwe           Great North Road, Chibombo         Central         Yes         Mumbwa           Shop No. 2 Zaf Mess Market, Mumbwa         Central         Yes         Kapiri Mposhi           Kapirimposhi         Central         Yes         Kapiri Mposhi           Kawama Market, Kawama Road,         Central         Yes         Kapiri Mposhi           Kapirimposhi         Central         Yes         Kapiri Mposhi           Kapirimposhi         No         Chipangali         No           Kapirimposhi         No         Chipangali         No           Kapirimposhi         No         Chipangali           MadziAtuwa Trading Centre         Eastern         No         Nyimba           Saronabi Complex, Great East Road         Eastern         No         Nyimba           Nyimba Main Market         Eastern         No         Lumezi		Jeabi Health Shop,	Bankers Area, Along Munkoyo Street, Kabwe	Central	Yes	Kabwe	Yes	
Great North Road, Chibombo     Central     Yes     Chibombo       Mulcke, Extension, Off Ndeke Dam Road,     Central     Yes     Kapiri Mposhi       Kayairimposhi     Central     Yes     Kapiri Mposhi       Kayaman Market, Kawama Road,     Central     Yes     Kapiri Mposhi       Kapasa Trading Centre     Eastern     No     Chipangali       Chipangali Trading Centre     Eastern     No     Chipangali       Madzi Atuwa Trading Centre     Eastern     No     Chipangali       Mac Amon, Great East Road     Eastern     No     Nyimba       Saronabi Complex, Great East Road     Eastern     No     Nyimba       Nyimba Main Market     Eastern     No     Lumezi       Plot No. 62, Lumezi Trading Center     Eastern     No     Lumezi       Plot No. 53, Lumezi Trading Area     Eastern     No     Lumezi       Along Great East Road, Chanjobou C.     Eastern     No     Lumezi		M. Sanyambe Health Shop	Shop No. 29, Kachulu Market, Kachulu Street, Kabwe	Central	Yes	Kabwe	Yes	
, b. Limited, Limited,Shop No. 2 Zaf Mess Market, Mumbwa RapirimposhiCentralYesMumbwa Rapiri Mpoship. KapirimposhiCentralYesKapiri Mpoship. KapirinyoshiCentralYesKapiri Mposhikapasa Trading CentreEasternNoChipangalireChipangali Trading CentreEasternNoChipangalireChipangali Trading CentreEasternNoChipangalireMadzi Atuwa Trading CentreEasternNoNyimbacySaronabi Complex, Great East RoadEasternNoNyimbacySaronabi Complex, Great East RoadEasternNoNyimbacySaronabi Complex, Great East RoadEasternNoNyimbaplot No. 62, Lumezi Trading CenterEasternNoLumeziplot No. 53, Lumezi Trading AreaEasternNoLumeziplot No. 53, Lumezi Trading AreaEasternNoLumeziplot No. 53, Lumezi Trading AreaEasternNoLumezi		Medilane Health Shop,	Great North Road, Chibombo	Central	Yes	Chibombo	Yes	
Nodeke Extension, Off Ndeke Dam Road, Central Yes Kapiri Mposhi Kapirimposhi Kawama Road, Central Yes Kapiri Mposhi Kapirimposhi Kapasa Trading Centre Eastern No Chipangali Trading Centre Eastern No Chipangali Chipangali Trading Centre Eastern No Chipangali Mac Amon , Great East Road Eastern No Nyimba Main Market East Road Eastern No Nyimba Myimba Main Market Eastern No Nyimba Morinda Main Market Eastern No Nyimba Morinda Main Market Eastern No Lumezi Plot No. 62, Lumezi Trading Center Eastern No Lumezi Diot No. 63, Lumezi Trading Area Eastern No Sinda Sinda		Phiojo Health Shop,	Shop No. 2 Zaf Mess Market, Mumbwa	Central	Yes	Mumbwa	Yes	
PyKawama Market, Kawama Road, KapiriMposhiCentralYesKapiri MposhireKapiriMposhiDoChipangalireChipangali Trading CentreEasternNoChipangalireMadzi Atuwa Trading CentreEasternNoChipangalireMadzi Atuwa Trading CentreEasternNoNyimbarySaronabi Complex, Great East RoadEasternNoNyimbaryNyimba Main MarketEasternNoNyimbaplot No. 62, Lumezi Trading CenterEasternNoLumeziplot No. 53, Lumezi Trading AreaEasternNoLumezidong Great East Road, Chanjobvu C.EasternNoSinda		Rhema Health Shop Limited,	Ndeke Extension, Off Ndeke Dam Road, Kapirimposhi	Central	Yes	Kapiri Mposhi	Yes	
Kapasa Trading CentreEasternNoChipangalireChipangali Trading CentreEasternNoChipangalireMadziAtuwa Trading CentreEasternNoNyimbacySaronabi Complex, Great East RoadEasternNoNyimbacySaronabi Complex, Great East RoadEasternNoNyimbanNyimba Main MarketEasternNoNyimbaplot No. 62, Lumezi Trading CenterEasternNoLumeziplot No. 53, Lumezi Trading AreaEasternNoLumeziAlong Great East Road, Chanjobvu C.EasternNoLumezi		Sky-Jay Health Shop,	Kawama Market, Kawama Road, KapiriMposhi	Central	Yes	Kapiri Mposhi	Yes	
reeChipangali Trading CentreEasternNoChipangalireMadziAtuwa Trading CentreEasternNoChipangalicySaronabi Complex, Great East RoadEasternNoNyimbacySaronabi Complex, Great East RoadEasternNoNyimbacyNyimba Main MarketEasternNoNyimbaplot No. 62, Lumezi Trading CenterEasternNoLumeziplot No. 53, Lumezi Trading AreaEasternNoLumeziAlong Great East Road, Chanjobvu C.EasternNoSinda		Leya Health Shop	Kapasa Trading Centre	Eastern	No	Chipangali	No	
reeMadziAtuwa Trading CentreEasternNoChipangaliSySaronabi Complex, Great East RoadEasternNoNyimbaSySaronabi Complex, Great East RoadEasternNoNyimbaNyimba Main MarketEasternNoNyimbaPlot No. 62, Lumezi Trading CenterEasternNoLumeziPlot No. 53, Lumezi Trading AreaEasternNoLumeziAlong Great East Road, Chanjobvu C.EasternNoSinda		Uncle Vin Drug Store	Chipangali Trading Centre	Eastern	No	Chipangali	No	
Saronabi Complex, Great East RoadEasternNoNyimbaNyimba Main MarketEasternNoNyimbaPlot No. 62, Lumezi Trading CenterEasternNoLumeziPlot No. 53, Lumezi Trading AreaEasternNoLumeziAlong Great East Road, Chanjobvu C.EasternNoSinda		Uncle Vin Drug Store	MadziAtuwa Trading Centre	Eastern	No	Chipangali	No	
cySaronabi Complex, Great East RoadEasternNoNyimbaNyimba Main MarketEasternNoNyimbaPlot No. 62, Lumezi Trading CenterEasternNoLumeziPlot No. 53, Lumezi Trading AreaEasternNoLumeziAlong Great East Road, Chanjobvu C.EasternNoSinda		Nyimba West Gate	Mac Amon ,Great East Road	Eastern	No	Nyimba	Yes	
Nyimba Main MarketEasternNoNyimbaNyimba Main MarketEasternNoNyimbaPlot No. 62, Lumezi Trading CenterEasternNoLumeziPlot No. 53, Lumezi Trading AreaEasternNoLumeziAlong Great East Road, Chanjobvu C.EasternNoSinda		Rehooboth Pharmacy	Saronabi Complex, Great East Road	Eastern	No	Nyimba	Yes	
Nyimba Main MarketEasternNoNyimbaPlot No. 62, Lumezi Trading CenterEasternNoLumeziDot No. 53, Lumezi Trading AreaEasternNoLumeziAlong Great East Road, Chanjobvu C.EasternNoSinda		Pembele Pharmacy	Nyimba Main Market	Eastern	No	Nyimba	Yes	
Op       Plot No. 62, Lumezi Trading Center       Eastern       No       Lumezi         Op       Plot No. 53, Lumezi Trading Area       Eastern       No       Lumezi         Along Great East Road, Chanjobvu C.       Eastern       No       Sinda		Fountain Pharmacy	Nyimba Main Market	Eastern	No	Nyimba	Yes	
JhopPlot No. 53, Lumezi Trading AreaEasternNoLumeziAlong Great East Road, Chanjobvu C.EasternNoSinda		M Care Pharmacy	Plot No. 62, Lumezi Trading Center	Eastern	No	Lumezi	Yes	
Along Great East Road, Chanjobvu C. Eastern No Sinda		Diamat Health Shop	Plot No. 53, Lumezi Trading Area	Eastern	No	Lumezi	Yes	
		Sinda Pharmacy	Along Great East Road, Chanjobvu C.	Eastern	No	Sinda	Yes	

Š.	Pharmacy	Address	Province	ZAMRA	Location	Local Authority Registration
193	M Care Pharmacy	Along Great East Road, Tiyeseko C.	Eastern	oN	Sinda	Yes
194	5 Star Pharmacy	Along G E Road, Sinda Old Market	Eastern	No	Sinda	No
195	Royal Care Health Shop	Nyanje Main Market	Eastern	No	Sinda	Yes
196	Agilbz Business Solution	Old Market	Eastern	No	Chadiza	No
197	Ashars General Dealer	Old Market	Eastern	No	Chadiza	No
198	Elroi Health Shop	Old Market	Eastern	oN	Chadiza	No
199	Tavern Life Enterprise	Old Market	Eastern	No	Chadiza	No
200	Chanida Border	Chanida Border	Eastern	No	Chadiza	No
201	Blink Pharmacy	Shop No. 4, Roadview Park Shopping Complex, Kitwe	Copperbelt	Yes	Kitwe	Yes
202	Chemopharm Limited	Shop No. 3, Matuka Avenue, Kitwe	Copperbelt	Yes	Kitwe	Yes
203	Chemopharm Limited	Plot No.87/88, Shop 1, Langashe Street, Po Box 21202, Kitwe	Copperbelt	Yes	Kitwe	Yes
204	Clinch Chemist	Plot No. 1a, Lwanshimba Road, Chamboli Market, Kitwe	Copperbelt	Yes	Kitwe	Yes
205	Cloverleaf Pharmacy Limited	Plot No. 139, Oxford Avenue, Kitwe	Copperbelt	Yes	Kitwe	Yes
206	East Health Pharmmacy	Plot No. 123, Buchi Road, Buchi, Kitwe	Copperbelt	Yes	Kitwe	Yes
207	Esvee Medicare	Stand No. 209, Chingola Road, Buchi, Kitwe	Copperbelt	Yes	Kitwe	Yes
208	Health Springs Pharmacy	Shop No. 5, Jambo Drive, Kitwe	Copperbelt	Yes	Kitwe	Yes
209	Jem Pharmacy	Plot No. 235, Joy Plaza, Kwacha Road, Kitwe	Copperbelt	Yes	Kitwe	Yes
210	Kharis Healthcare Compant Limited	Plot No. 68, Kafwimbi Street, Kwacha East, Kitwe	Copperbelt	Yes	Kitwe	Yes

No.	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration
211	Link Pharmacy	Stand 6936, Shop No. 030, Mukuba Mall, Chiwala Avenue, Kitwe	Copperbelt	Yes	Kitwe	Yes
212	Lupharm Pharmacy	Plot No. 28, Shop No. 3, Enos Chomba Road, Kitwe	Copperbelt	Yes	Kitwe	Yes
213	Lupharm Pharmacy	Plot No. 2557, Obote Avenue, Kitwe	Copperbelt	Yes	Kitwe	Yes
214	Mambo's Chemist Limited	Plot No. 277, Obote Avenue, Kitwe	Copperbelt	Yes	Kitwe	Yes
215	Med Corp Pharmacy Limited	Plot No. 123d, Langashe Street, Kitwe	Copperbelt	Yes	Kitwe	Yes
216	Mwechi Pharmacy Limited	Plot No. 37, Tafiwa Drive, Ndeke, Kitwe	Copperbelt	Yes	Kitwe	Yes
217	Truecare Pharmacy Limited	Plot No. 70, Shop 4, Kawama Road, Kitwe	Copperbelt	Yes	Kitwe	Yes
218	Union Chemist Limited	Plot No. 18, Shop No. 5, Obote Avenue, Kitwe	Copperbelt	Yes	Kitwe	Yes
219	Mandela Health Pharmacy	Ganerton	Copperbelt	No	Kitwe	No
220	Kawani Pharmacy	Chimwemwe Lima Clinic 1	Copperbelt	No	Kitwe	Yes
221	Pharmmaid Pharmacy	Racecourse Market Road	Copperbelt	No	Kitwe	No
222	Chimwemwe Pharmacy	Chimwemwe Kamunga	Copperbelt	No	Kitwe	No
223	Joy Of Life Pharmacy	Chimwemwe	Copperbelt	No	Kitwe	No
224	Pa And E Drug Store	Kawama	Copperbelt	No	Kitwe	No
225	Biomed Care Pharmacy	Chimwemwe	Copperbelt	No	Kitwe	No
226	Purity Drug Store	Old Nakadoli	Copperbelt	No	Kitwe	No
227	Dabs Drug Store	Old Nakadoli	Copperbelt	No	Kitwe	No
228	Chilu Health Care	Chimwemwe	Copperbelt	No	Kitwe	No
229	Numfundu Drug Store	Chimwemwe	Copperbelt	No	Kitwe	Yes

2	Dharmacv	o o o i o i	Province	ZAMRA	Location	Local Authority
		999,550		Registration		Registration
230	Trucare	Kawama 722	Copperbelt	No	Kitwe	Yes
231	Lubelele Pharmacy	Kamunga Chimwemwe	Copperbelt	No	Kitwe	Yes
232	Tasimas Links Health Shop	Kawama 722	Copperbelt	No	Kitwe	Yes
233	Afrogreen Pharmacy	Kamunga Chimwemwe	Copperbelt	No	Kitwe	No
234	Makcla Pharmacy	Chimwemwe	Copperbelt	No	Kitwe	No
235	Mwananshila Drug Store	Chimwemwe Kamunga	Copperbelt	No	Kitwe	No
236	Kalo Family Comm. Medical Pharm.	Chimwemwe Chishiba Road	Copperbelt	No	Kitwe	No
237	KawamaKafindondo Drug Store	Kawama	Copperbelt	oN	Kitwe	Yes
238	Amotek Pharmacy	Chimwemwe	Copperbelt	No	Kitwe	Yes
239	Biotrust Pharmacy	Chimwemwe	Copperbelt	No	Kitwe	Yes
240	Chimwemwe Medicare Pharmacy	Chimwemwe	Copperbelt	No	Kitwe	Yes
241	Evergreen Pharmacy	Chimwemwe	Copperbelt	No	Kitwe	Yes
242	Christopher Banda Drug Store	Kamatipa	Copperbelt	No	Kitwe	No
243	Izukanji Health Shop	Kamatipa	Copperbelt	No	Kitwe	No
244	Dakamu Health Shop	Kamatipa	Copperbelt	No	Kitwe	No
245	Yamikani Drug Store	Kamatipa	Copperbelt	No	Kitwe	No
246	Elvis Mwape Drug Store	Kamatipa	Copperbelt	No	Kitwe	No
247	Mik Med Pharmacy	Ndola Kitwe Dual Carriage Way	Copperbelt	No	Kitwe	Yes
248	Across Fronties Drug Store	Luangwa Market	Copperbelt	No	Kitwe	Yes

No.	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration
249	Penda Pharmacy	Luangwa Market	Copperbelt	No	Kitwe	Yes
250	DiaruusChalwe Drug Store	WusakileMiseshi	Copperbelt	No	Kitwe	No
251	Ireen Mwape Drug Store	WusakileMiseshi	Copperbelt	No	Kitwe	No
252	Ilu Chemist	WusakileMiseshi	Copperbelt	No	Kitwe	No
253	Miseshi Pharmacy	MukubaNatwange	Copperbelt	No	Kitwe	Yes
254	Footprint Pharmarcy	MukubaNatwange	Copperbelt	No	Kitwe	Yes
255	MwechiPharmarcy	Ndeke Village	Copperbelt	No	Kitwe	Yes
256	MwechiPharmarcy	Masuzyo	Copperbelt	No	Kitwe	Yes
257	Criss More Health Shop	Changa	Copperbelt	No	Kitwe	No
258	Lomex Pharmacy	MukubaNatwange	Copperbelt	No	Kitwe	Yes
259	Walini Pharmacy	Amis	Copperbelt	No	Kitwe	Yes
260	BabraMawhite Drug Store	2526 C Kwacha East	Copperbelt	No	Kitwe	No
261	Bonabel Pharmacy	Plot 6338 Jambo Drive Riverside	Copperbelt	No	Kitwe	Yes
262	Ritemed Pharmacy	Plot 7713 Almalik Riverside	Copperbelt	No	Kitwe	Yes
263	Lesante Pharmacy	Plot 8673 Jambo Drive Riverside	Copperbelt	No	Kitwe	Yes
264	Microwin Pharmacy	Plot 6710 Central Street Nkana East	Copperbelt	No	Kitwe	Yes
265	Vyiking Pharmacy	Mwaiseni Road Nkana East	Copperbelt	No	Kitwe	Yes
266	East Health Pharmaacy	Central Street Nkana East	Copperbelt	No	Kitwe	Yes
267	Alpha Drug Store	Bulangililo Market	Copperbelt	No	Kitwe	No
268	Mishmosi Drug Store	Bulangililo Market	Copperbelt	No	Kitwe	Yes

No.	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration
269	Kharis Pharmacy	Plot 68 Kwacha East	Copperbelt	No	Kitwe	Yes
270	Nchanga Chemist	02 Miler Building	Copperbelt	No	Kitwe	No
271	Eagle Chemist	Plot 19, Town Centre	Copperbelt	No	Kitwe	Yes
272	Bantu Pharmacy	Shop No 05	Copperbelt	No	Kitwe	Yes
273	Rokana Chemist	13 Matuka Ave	Copperbelt	No	Kitwe	Yes
274	Clover Leaf Pharmacy	Oxford Road	Copperbelt	No	Kitwe	Yes
275	Serve The World Pharmacy	Oxford Road	Copperbelt	No	Kitwe	Yes
276	Copper Chemist	Oxford Road	Copperbelt	No	Kitwe	Yes
277	Royal Chemist Pharmacy	Matuka	Copperbelt	No	Kitwe	No
278	Chemopharm Pharmacy	Second Class	Copperbelt	No	Kitwe	Yes
279	Esvee Pharmacy	Obote	Copperbelt	No	Kitwe	No
280	Vyking Pharmacy	Obote	Copperbelt	No	Kitwe	Yes
281	Lusaka Pharmacy	Enos Chomba	Copperbelt	No	Kitwe	Yes
282	Ab Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
283	Ads Pharmacy	Plot No. 9145, Chisokone/Blantyre Road, Ndola	Copperbelt	Yes	Ndola	Yes
284	Alchamist Zambia Limited	Plot No. 268/61, Ndola	Copperbelt	No	Ndola	Yes
285	Alen Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
286	Atlas Chemist	Not provided	Copperbelt	No	Ndola	Yes
287	Baxy Pharmaceuticals Co. Limited.	Not provided	Copperbelt	No	Ndola	Yes

No.	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration
288	Bietechem Care Pharmacy Limited	Plot No. Nt 001/02, Ndola Villa, Mwanawasa Road, Ndola	Copperbelt	Yes	Ndola	Yes
289	Biotec Pharmaceuticals	Not Provided	Copperbelt	No	Ndola	Yes
290	Briking Limited T/A Kansenji Chemist	Plot No. 70956, Shop No. 7, Hillcrest, Ndola	Copperbelt	Yes	Ndola	Yes
291	Briking Limited T/A Kansenji Chemist	Plot No. 2136, Kwacha Road, Kansenshi, Ndola	Copperbelt	Yes	Ndola	Yes
292	Bunes Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
293	Carliner Chemist Limited	Not provided	Copperbelt	No	Ndola	Yes
294	Charikam Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
295	Chermo Pharm	Not provided	Copperbelt	No	Ndola	Yes
296	Chinon Medical Centre	Not provided	Copperbelt	No	Ndola	Yes
297	Dimpo's Chemist Limited	Plot No. 2136, Kwacha Road, Kansenshi, Ndola	Copperbelt	Yes	Ndola	Yes
298	Equity Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
299	Gratitude Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
300	Green Shop Pharmacy Limited	Not provided	Copperbelt	No	Ndola	Yes
301	Healthcure Pharmacy	Plot No. Ch 122, Ndola	Copperbelt	Yes	Ndola	Yes
302	Hosea Chemist	Not provided	Copperbelt	No	Ndola	
303	Jacaranda Pharmacy	Shop No. 26, Jacaranda Mall, Ndola	Copperbelt	Yes	Ndola	Yes
304	Jakambo Pharmacy	Shop No. 8, Chimwemwe Road, Town Centre, Ndola	Copperbelt	Yes	Ndola	Yes
305	Jomasi Pharmacy	Not provided	Copperbelt	No	Ndola	Yes

:	i			ZAMRA		Local Authority
OZ	Pnarmacy	Address	Province	Registration	Location	Registration
306	Kaycee Pharmacy	Plot No. 29/30, Kawambwa Road, Masala, Ndola	Copperbelt	Yes	Ndola	Yes
307	Link Pharmacy	Shop No. 8, Villa Shopping Mall, Ndola	Copperbelt	Yes	Ndola	Yes
308	Materia Medica Pharmacy Limited	Plot No. 3 & 4, Kabwe Road, Ndola	Copperbelt	Yes	Ndola	Yes
309	Matex Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
310	Medicpharm Chemist	Not provided	Copperbelt	No	Ndola	Yes
311	Mediway Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
312	Melcome Pharmaceuticals Co.Limited	Not provided	Copperbelt	No	Ndola	Yes
313	Modern Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
314	Mpharm Pharmaceuticals	Not provided	Copperbelt	No	Ndola	Yes
315	Mubothu Pharmacy Limited	Not provided	Copperbelt	No	Ndola	Yes
316	Mushili Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
317	Mycare Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
318	Ndola Chemist 1979 Limited.	Not provided	Copperbelt	No	Ndola	Yes
319	Noor Pharmaceuticals	Not provided	Copperbelt	No	Ndola	Yes
320	Pamodzi Roadside Chemist Limited	Plot No. 18, Shop No. 5, President/Blantyre Road, Ndola	Copperbelt	Yes	Ndola	Yes
321	Pharmanova Zambia Limited	Not provided	Copperbelt	No	Ndola	Yes
322	Proven Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
323	Ryino Pharmacy Limited	Not provided	Copperbelt	No	Ndola	Yes

O N	Pharmacy	Address	Province	ZAMRA Registration	Location	Local Authority Registration
324	Seven Star Pharmacy	Not provided	Copperbelt	No	Ndola	Yes
325	ShashaPharmaceuitcals And Gen. Dealers	Not provided	Copperbelt	Ň	Ndola	Yes
326	Silkan Pharmacy Limited	Not provided	Copperbelt	No	Ndola	Yes
327	SonjayLittla Your Chemist	Not provided	Copperbelt	No	Ndola	Yes
328	Sree Pharmaceuticals	Not provided	Copperbelt	No	Ndola	Yes
329	Swiza Laboratories	Not provided	Copperbelt	No	Ndola	Yes
330	Tisha Pharmacy Limited	Not provided	Copperbelt	No	Ndola	Yes
331	Trumed Pharmacy	Plot 1925, Shop No. 13a, Kafubumall, Cnr President Ave & The T3 Highway, Ndola	Copperbelt	Yes	Ndola	Yes
332	Unimex Chemicals	Not provided	Copperbelt	No	Ndola	Yes
333	Vida Pharmacy Enterprise	Not provided	Copperbelt	No	Ndola	Yes
334	Vita Liye Pharmaceuticals	Not provided	Copperbelt	No	Ndola	Yes
335	Welvis Pharmacy Limited	Not provided	Copperbelt	No	Ndola	Yes
336	Yash Pharmaceuticals	Not provided	Copperbelt	No	Ndola	Yes
337	Your Chemist	Plot No. 174, Masala Road, Masala Main, Ndola	Copperbelt	Yes	Ndola	Yes
338	Real Ways	Manyama	North Western	No	Kalumbila	Yes
339	J.Makungu	Manyama	North Western	No	Kalumbila	Yes
340	Sandu	Manyama	North Western	No	Kalumbila	Yes
341	Blink Pharmacy	Manyama	North Western	No	Kalumbila	Yes
342	AcksonKawangu	Kisasa	North Western	No	Kalumbila	Yes

Pharmacy		Address	Province	ZAMRA Registration	Location	Local Authority Registration
Mbangu Kisasa	Kisasa		North Western	No	Kalumbila	Yes
Messitazah Medical Services And General Dealers	Kisasa		North Western	No	Kalumbila	Yes
345 Stanley Chishimba Health Shop Kisasa	Kisasa		North Western	No	Kalumbila	Yes
Sure Drug Store Kisasa	Kisasa		North Western	No	Kalumbila	Yes
347 Pharmaking Kalumbila	Kalumbila		North Western	No	Kalumbila	Yes
Healthcure Pharmacy Kalumbila	Kalumbila		North Western	No	Kalumbila	Yes
349 Nema Drug Store Maheba 36	Maheba 36		North Western	No	Kalumbila	Yes
Sedestian Drugstore Maheba 36	Maheba 36		North Western	No	Kalumbila	Yes
351 Rapha Drugstore Maheba 36	Maheba 36		North Western	No	Kalumbila	Yes

Appendix 8: Public and Private Hospital Pharmacies Inspected

S/N	Province	District	Facility	ZAMRA
5/IV	TTOVITICE	District	1 acmty	Registration
		Pub	lic Hospital Pharmacy	
1	Lusaka	Lusaka	UTH Adult Pharmacy	No
2	Lusaka	Lusaka	UTH Paedriatics Hospital Pharmacy	No
3	Lusaka	Lusaka	Levy Mwanawasa Pharmacy	No
4	Lusaka	Lusaka	Matero L1 Hospital	No
5	Lusaka	Lusaka	Matero Main Health centre	No
6	Lusaka	Lusaka	Chipata L1 Hospital	No
7	Lusaka	Lusaka	Kanyama General Hospital	No
8	Lusaka	Lusaka	Chawama General Hospital	No
9	Lusaka	Lusaka	George Health Centre	No
10	Lusaka	Lusaka	John Howard Health Post	No
11	Lusaka	Lusaka	Kabwata Health Centre	No
12	Lusaka	Lusaka	Chilenje Level 1 Hospital	No
13	Lusaka	Lusaka	State House Urban Health Centre	No
14	Lusaka	Lusaka	Railway Health Centre	No
15	Lusaka	Lusaka	Kamwala Health Centre	No
16	Lusaka	Lusaka	Chelston Zonal Hospital	No
17	Lusaka	Lusaka	Chainda Health Centre	No
18	Lusaka	Lusaka	Kalingalinga Health Centre	No
19	Lusaka	Kafue	Kafue General Hospital	No
20	Copperbelt	Ndola	Ndola Teaching Hospital	Yes
21	Copperbelt	Ndola	Ndeke Mini Hospital	No
22	Copperbelt	Ndola	Twapia Urban Health Centre	No
23	Copperbelt	Ndola	Lubuto Clinic	No
24	Copperbelt	Ndola	Masala Clinic	No
25	Copperbelt	Ndola	Kawama Clinic	No
26	Copperbelt	Ndola	Railway surgery Clinic	No
27	Copperbelt	Ndola	ChipokotaMayamba Clinic	No
28	Copperbelt	Ndola	ArthurDavison Children's Hospital	No
29	Copperbelt	Kitwe	Ndeke Mini Hospital	No
30	Copperbelt	Kitwe	Riverside Clinic	No
31	Copperbelt	Kitwe	Kwacha Clinic	No
32	Copperbelt	Kitwe	Buchi Main Clinic	No
33	Copperbelt	Kitwe	Bulangililo Clinic	No
34	Copperbelt	Kitwe	Wusakile Mine Hospital	No
35	Copperbelt	Kitwe	Nkana East Health centre	No
36	Copperbelt	Kitwe	Luangwa Urban Health Centre	No

**ZAMRA** S/N **Province District Facility** Registration Mulenga Urban Health Centre 37 Copperbelt Kitwe No 38 Copperbelt Kitwe Kitwe Teaching hospital No 39 Copperbelt Mufulira Ronald Ross General Hospital No 40 Copperbelt Chingola Chiwempala Clinic No 41 Copperbelt Chingola Kabundi East Clinic No 42 Central KapiriMposhi KapiriMposhi District Hospital No 43 Central KapiriMposhi Chawama Health Centre No 44 TAZARA Clinic Central KapiriMposhi No 45 Chibombo Central Chibombo Rural Health centre No 46 Chibombo Central Liteta District Hospital No 47 Kabwe Central Kabwe Central Hospital No 48 Central Kabwe Mahatma Ghandi Memorial Clinic No 49 Southern Livingstone Livingstone Teaching Hospital No Southern **50** Chirundu Mtendere Mission Hospital No 51 Southern Kazungula Kazungula District Hospital No 52 Southern Mazabuka Mazabuka General Hospital Yes No 53 Western Mongu District Hospital Mongu 54 Western Mongu Lewanika General Hospital No Western Prisons Clinic 55 Mongu No Western **56** Senanga Senanga General Hospital No 57 Western No Senanga Senanga Urban Clinic Western Kaoma **58** Kaoma District Hospital No 59 Western Kaoma Mulamba Urban Clinic No Western No 60 Kaoma Luena Camp Hospital 61 Eastern Chipata Walela Health Post No 62 No Eastern Katete Katete General Hospital **Private Hospital Pharmacy** Lusaka Lusaka Yes 1 Mums Care Hospital 2 Ruth Kaluluma Memorial Hospital Lusaka Lusaka Yes Lusaka 3 Lusaka Lusaka Trust Hospital Yes 4 Copperbelt Kitwe Yes Progress Hospital 5 Copperbelt Ndola Mary Begg Hospital Yes Nico Memorial Clinic Southern Kazungula 6 Yes Sebry Clinic 7 Southern Chirundu No 8 Eastern Chipata Altaf Memorial Hospital No

Appendix 9: Physical Inspection Findings on Unregistered Premises

Prescription Book	Smart Care	Smart	N N	Updated	Yes	Yes	Yes	9 N	Yes	Yes	Yes	Yes	Yes	Yes	No No	Yes	Yes	Yes	Yes	No	o N	Yes	Yes	Yes
DDA	Yes	Yes	2	2	Yes	2	2	2	N <sub>o</sub>	2	8	N <sub>o</sub>	8	N N	2	§.	2	2	2	2	2	2	Yes	S S
NDPSA	Yes	o <sub>N</sub>	No No	No No	Yes	No	2	2	2	2	2	N <sub>O</sub>	2	9 9	o <sub>N</sub>	No	9 2	2	2	No	2	2	Yes	8
НРА	Yes	Yes	8	8 8	Yes	No	o N	8	8	o N	8	9N	8	No No	8	% S	8	2	2	No	<sup>o</sup> Z	Yes	Yes	8
MASA	S S	Yes	8	No No	Yes	No	o <sub>N</sub>	2	2	2	2	2	2	8	S S	No No	8	9	9	No	8 N	9	Yes	2
STG	Yes	Yes	8	Yes	Yes	No	S S	S S	S S	S <sub>O</sub>	S S	Yes	8	N <sub>o</sub>	8	N N	8	Yes	8	No	Š	No	Yes	S S
ZNF	2	2	2	Yes	Yes	No No	8	Yes	8 8	Yes	Yes	Yes	8	No No	2	2	2	ટ	2	No	8 N	%	Yes	8
Sops Available On Site	N S	Yes	<sub>S</sub>	Yes	Yes	Yes	8	Yes	Yes	No	Yes	o N	8	8	9 8	No	Yes	N <sub>o</sub>	No.	No	oN N	Yes	Yes	Yes
Dangerous Drug Register	2	Not Updated	2	Yes	2	Yes	Yes	Yes	Yes	Not Updated	Updated	Not Updated	Updated	Not Updated	Not Updated	Not Updated	Yes	Yes	2	No	°N	Yes	Yes	Yes
Expired Drugs Register	Ŷ.	Updated	oN N	Updated	Yes	Yes	Ŷ.	9	Yes	2	8	Yes	Yes	Yes	Not Updated	Not Updated	Yes	% %	Yes	No	°N	Yes	Yes	o <sub>N</sub>
Dangerous Drugs Cupboard	Secured	Secured	Secured	Not Secured	Not Secured	Not Secured	Secured	Secured	Secured	No	o <sub>N</sub>	Not Labelled, Not Secured	Secured	Secured	Not Secured	Not Secured, NL	N/A	Yes	No	Not Secured	Yes	No	Yes	Yes
Expired Drugs Area	N <sub>O</sub>	Yes NL	No No	Yes	9	Yes	2	Yes	9	9	Yes	Yes	9N	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No.	Yes	Yes
Running Water	Yes	Yes	Yes	Yes	Yes	Yes	o <sub>N</sub>	Yes	Yes	Yes	Yes	o <sub>N</sub>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Updated Temp. Charts	Updated	Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Updated	Not Updated		Not Updated	Not Updated	Not Updated	Not Updated	
	pdn	Pdn	Not	Not	Not	Not	Not	Not	Not	Not	pdn	Not	Not	Not	Not	Not	pdn	Not	2	Not	Not	Not	Not	Yes
Thermometer Reading (Celsius)	21	19	22°	21	19°	26°	No Thermometre	26°	22°	21	19	21	23	19	22	21	22	20	N <sub>o</sub>	20	20	25	18	16
Ventilation	Poor	Good	Good	Good	Good	Poor	Poor	Good	Good	Poor	Good	Good	Good	Poor	Poor	Good	Good	Good	Good	Good	Good	Good	Good	Good
Ceiling	Poor Condition	Good	Good	Good	Good	Good	Poor Condition	Good	Good	Good	Poor	Good	Good	Good	Good	Poor	Good	Good	Poor	Good	Good	Good	Good	Good
Presence Of Pharmadist	Yes	Pharmtech	Yes	Yes	Yes	Yes	Non Pharm	Yes	Yes	Pharmtech	Yes	Pharmtech	Yes	Pharmtech	Pharamc	Pharmadist	Yes	Pharmtech	Non Pharm	Pharmtech	Pharmtech	Pharmtech	Yes	Pharmtech
Valid HPCZ Practicing Licensing	Yes	Yes	Yes	Yes	Yes	Yes	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	N/A	Yes	Yes	Yes	Yes	Yes
ZAMRA Registration	<u>8</u>	9	2	9	oN N	No	N <sub>o</sub>	oN N	oN N	oN N	oN N	o <sub>N</sub>	N N	No	N N	No	8	2	9 N	No	o N	No	No	ON O
Health Facility	George Health Centre	Matero Main Health Centre	Materol Level 1 Hospital	Chipata Level1 Hopsital	Kanyama General Hospital	Chawama General Hospital	John Howard Health Post	Kabwata Health Centre	Chilenje Level 1 Hospital	State House Urban Health Centre	Railway Health Centre	Kamwala Health Centre	Chelstone Zonal Hospital	Chainda Health Centre	Kalingalinga Health Centre	Kafue General Hospital	Mtendere Mission Hospital	Masala Clinic	Ndeke Mini Hospital	ChipokotaMayamba Clinic	Twapia Urban Health Centre	Lubuto Clinic	Auther Davison Hospital	Kawama Clinic
District	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Kafue	Chirundu	Ndola	Ndola	Ndola	Ndola	Ndola	Ndola	Ndola
Province	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Southern	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt Ndola
				L															L				$\Box$	لــــــــــــــــــــــــــــــــــــــ

Prescription Book	Yes	Yes	Yes	Yes	Yes	No No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	<sub>o</sub> N	Yes
DDA	2	2	2	2	2	8	2	2	2	Yes	9 2	2	S.	2	2º	2	2	ટ	2	2	2	2
NDPSA	9	2	9	No No	Ŷ.	N <sub>O</sub>	2	2	2	Yes	2	2	8	2	2	8	No No	9	8	8	9	2
HPA	9	2	9 8	N <sub>O</sub>	- N	oN N	o N	2	2	Yes	2	2	o N	2	2	2	Yes	% %	2	2	9	2
MASA	9 N	8	9	9	9 8	o N	8	2	2	Yes	2	2	2	2	8	2	Yes	9	2	2	<sub>o</sub> N	% %
STG	No	N N	Yes	8	No	N <sub>O</sub>	8	<sub>o</sub> N	8	Yes	<sub>o</sub>	o N	N <sub>o</sub>	8	o <sub>N</sub>	8	Yes	2	8	Yes	ON	Yes
ZNF	S	2	2	Yes	2	9 N	8	ž	ž	Yes	2	ž	8	ž	Yes	Yes	Yes	Yes	2	2	2	2
Sops Available On Site	No No	Yes	Yes	Yes	oN N	No	Yes	Yes	Yes	Yes	N <sub>O</sub>	Yes	N N	Yes	Yes	Yes	N N	Yes	Yes	9N	No	Yes
Dangerous Drug Register	9	Yes	Yes	Yes	9	Yes	o N	Yes	Yes	Yes	N <sub>o</sub>	9N	o N	Updated	Not Updated	Updated	Updated	N/A	Yes	2	9	No
Expired Drugs Register	No No	Š.	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Updated	Updated	o N	Updated	Yes	Updated	Updated	Yes	Yes	Yes	Not Updated	Not Updated
Dangerous Drugs Cupboard	Yes	Yes	Yes	N/A	N <sub>o</sub>	Not Secured	o N	Secured	Secured	Secure	Not Secured	Not Secured	Secure	Secure	2	Secure	Yes	N/A	Not Secure	N N	No	Secure
Expired Drugs Area	o N	N N	2	2	Yes	No No	Yes	Yes	Yes	Yes	9	Yes	o N	8	N N	Yes	oN N	9 N	Yes	2	Yes	Yes
Running Water	Yes	Yes	Yes	9N	oN N	Yes	Yes	N N	S.	Yes	Yes	Yes	Yes	S.	Yes	2	Yes	Yes	Yes	Yes	Yes	Yes
Updated Temp. Charts	Not Updated	9	8	Not Updated	<u>8</u>	Not Updated	No Thermometer	No No	Not Updated	Yes	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated
Thermometer Reading (Celsius)	20	No Thermometer	21	22	No Thermometer	No Thermometer	O <sub>N</sub>	No Thermometer	No Thermometer	18	No Thermometer	Non Functional	No Thermomemter	20	21	23	No.	Yes	22	22	24	19
Ventilation	Good	Good	Good	Good	Good	Good	Good	Poor	Poor	Good	Poor	Good	o <sub>N</sub>	Poor	Poor	Good	Good	Good	Good	Good	Poor	Good
Ceiling	Good	Good	Good	Good	Good	Good	Yes	Good	Good	Good	Poor	Good	Good	Good	Good	Good	Poor	Good	Yes	Poor	Good	Good
Presence Of Pharmadist	Non Pharm	Pharmtech	Non Pharm	Non Pharm	Pharmtech	Non Pharm	Non Pharm	Pharmtech	Pharmtech	Yes	Pharmtech	Pharmtech	Non Pharm	Pharmtech	Non Pharm	Yes	Yes	Pharmtech	Pharmtech	Non Pharm	Pharmacydispenser	Pharmtech
Valid HPCZ Practicing Licensing	N/A	Yes	N/A	NA	Yes	N/A	ΝΆ	Yes	Yes	Yes	Yes	Yes	ON.	Yes	9 N	Yes	Yes	Yes	Yes	N/A	Yes	Yes
ZAMRA Registration	9 8	2	2	9	N N	No	N N	N <sub>o</sub>	8	N 8	N N	No	N N	8	N N	2	<u>8</u>	2	2	8	N N	No No
Health Facility	Railway Surgery Clinic	Ndeke Mini Hospital	Riverside Clinic	Kwacha Clinic	Buchi Main Clinic	Bulangililo Clinic	Nkana East Health Centre	Luangwa Urban Health Centre	Mulenga Urban Health Centre	Kitwe Teaching Hospital	Chiwempala Clinic	Kabundi East Clinic	TAZARA Clinic	KapiriMposhi District Hospital	Chawama Health Centre	Mongu District Hospital	Lewanika General Hospital	Prisons Clinic	Senanga General Hospital	Senanga Urban Clinic	Luena Camp Hospital	Kaoma District Hospital
District	Ndola	Kitwe	Kitwe	Kitwe	Kitwe	Kitwe	Kitwe	Kitwe	Kitwe	Kitwe	Chingola	Chingola	KapiriMposhi	KapiriMposhi	KapiriMposhi	Mongu	Mongu	Mongu	Senanga	Senanga	Kaoma	Kaoma
Province	Copperbelt	Copperbelt	Copperbelt	Copperbelt Kitwe	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt Chingola	Copperbelt	Central	Central	Central	Western	Western	Western	Western	Western	Western	Western

Province	District	Health Facility	ZAMRA Registration	Valid HPCZ Practicing Licensing	Presence Of Pharmacist	Ceiling	Ventilation	Thermometer Reading (Celsius)	Updated Temp. Charts	Running Water	Expired Drugs Area	Dangerous Drugs Cupboard	Expired Drugs Drugs Register	Dangerous S Drug Register	Sops Available On Site	ZNF S	STG M/	MASA HE	HPA NDF	NDPSA DDA		Prescription Book
Western	Kaoma	Mulamba Urban Clinic	8	No.	Non Pharm	Good	Good	Yes	Not Updated	Yes	Yes	Secure	Yes	9 8	No No	2	N N	No No	No No		N No	0
Central	Chibombo	Chibombo Rural Health Centre	2	Yes	Pharmtech	Good	Good	18	Updated	o <sub>N</sub>	Yes	Not Secure	Updated	Not Updated	Yes	2	% %	8	0N 0N		2	Yes
Central	Chibombo	Liteta District Hospital	8	Yes	Pharmtech	Poor	Good	23	Not Updated	Yes	Yes	Not Secure	Ŷ.	Not Updated	Yes	2			0N ON		% 	Yes
Central	Kabwe	KabweCentral Hospital	N S	Yes	Yes	Good	Good	18	Updated	Yes	Yes	Secured	Updated	Updated	Yes	2	N N	oN oN	No		% %	Yes
Central	Kabwe	Mahatma Ghandi Memorial Clinic	oN O	Yes	Pharmtech	Good	Good	22	Not Updated	Yes	Yes	Not Secure	Updated	Updated	Yes	9	 %	- N	No No		% 	Yes
Southern		Livingstone Teaching Hospital.	No No	No.	Pharmacist	Average	PooS	30	Not Updated	Yes	Yes NI	Secured	Yes	Yes	o N	Yes	Yes	Yes	Yes Yes		Yes Ye	Yes
Southern		Kazungula District Hospital	No	Yes	Non Pharm.Tech	Good	Good	30	Updated Temp.	Yes	YesL	Secured	Yes	YES	Yes	Yes	Yes	Yes	Yes Yes		Yes Ye	Yes
Southern		Safeway Health Shop	9	No.	Non Pharm Tech	Good	Average	28	Not Updated	Yes	2	N/A	9 8	9 8	o <sub>N</sub>	<sub>S</sub>	2 8	2	oN oN		% %	
Eastern		Walela Health Post	No	N/A	Non Pharm.	Fair	Good	30	Not Updated	Yes	No	Not Secured	No	No	No	Yes	No	Yes	Yes Yes		No	Yes
Eastern		Altaf Memorial Hospital	N N	Yes	Pharm.Tech	Fair	Good	23.4	Updated Temp	Yes	Yes NI	Secured	9 8	Yes	o <sub>N</sub>	N <sub>o</sub>	 	- - - - -	No No		No Ye	Yes
Eastern		Katete General Hospital	No	Yes	Pharmacist	Good	9009	19	Not Updated	Yes	Yes NI	Secured	Yes	Yes	No	No	Yes	Yes	Yes No		Yes Ye	Yes
Copperbelt Mufulira	Mufulira	Ronald Ross General Hospital	o N	Yes	Pharmacist	Fair	Good	30	Not Updated	Yes	Yes NI	Secured	9 N	Yes	o N	Yes	Yes	Yes	Yes Yes		Yes No	0
Lusaka	Lusaka	UTH Adult Pharmacy	No	Yes.	Yes	Very Poor	Good	24	Not Updated	Yes	Yes NI	Secured	Yes	Yes	Yes	Yes	Yes	Yes	Yes Yes		Yes Ye	Yes
Lusaka	Lusaka	UTH Pediatrics. Hospital Pharmacy	No	Yes	Pharmacist	Good	Good	23	Not Updated	No	Yes NI	Not Secured	Yes	No No	No	No	Yes	Yes	Yes Yes		Yes Ye	Yes
Lusaka	Lusaka	Levy Mwanawasa Pharmacy	o N	Yes	Pharmacist	Good	Good	26	Not Updated	Yes	YesL	Secured	Yes	Yes	9	Yes	Yes	Yes	Yes Yes		Yes	Yes

Appendix 10: List of Physically Inspected Registered Premises that have had a Post Licensing Inspection

No.	Province	District	Facility	COR	Number of inspections	post licensing inspections
1	Lusaka	Lusaka	Downtown Pharmacy	01.12.2017	1	22.10.2019
2	Lusaka	Lusaka	Save Life Pharmacy	31.01.2006	1	28.10.2020
3	Lusaka	Lusaka	Southwest Pharmacy	07.04.2021	1	02.07.2022
4	Lusaka	Lusaka	We Care Pharmacy	05.01.2018	3	• 13.03.2019 • 24.04.2019 • 09.11.2020
5	Lusaka	Lusaka	Jubilee Chemist	15.02.2000	1	21.08.2019
6	Lusaka	Lusaka	Lusaka Pharmaceutical Limited	16.05.2012	1	15.02.2021
7	Lusaka	Lusaka	Agrimac Pharmacy	02.09.2019	1	24.02.2022
8	Lusaka	Lusaka	M. Care Pharmacy	17.04.2014	2	• 11.06.2018 • 20.11.2021
9	Lusaka	Lusaka	Happy Pill	15.06.2016	1	12.2021
10	Lusaka	Kafue	The Things Pharmacy	6.10.2017	4	• 06.11.2017 • 05.04.2018 • 05.09.2018 • 04.01.2018
11	Southern	Chirundu	Kandende Pharmacy and Cosmetic Limited	23.12.2021	2	<ul><li>23.05.2022</li><li>06.07.2022</li></ul>
12	Southern	Chirundu	Skyline Best Health care - Health Shop	28.06.2021	2	• 11.03.2022 • 15.03.2022
13	Southern	Chirundu	Chirundu Pharmacy	04.05.2018	5	• 06.12.2019 • 19.07.2021 • 05.08.2021 • 21.09.2021 • 23.05.2022
14	Copperbelt	Ndola	Welvis Pharmacy	06.10.2020	1	20.11.2020
15	Copperbelt	Ndola	Green Shop Pharmacy	13.05.2020	2	• 04.11.2020 • 27.05.2020
16	Copperbelt	Ndola	Mas Health shop	29.06.2021	1	03.12.2021
17	Copperbelt	Ndola	AB Pharmacy	03.08.2021	1	16.03.2021
18	Copperbelt	Ndola	Charikam Pharmacy Limited	04.01.2021	2	• 16.07.2021 • 09.09.2021
19	Copperbelt	Kitwe	Mik Med Pharmacy Limited	14.09.20	2	• 09.10.2020 • 09.06.2021

No.	Province	District	Facility	COR	Number of inspections	post licensing inspections
20	Copperbelt	Kitwe	Joy of Life Pharmacy	27.01.2022	1	04.03.2022
21	Copperbelt	Kitwe	Chimwemwe Medicare Pharmacy Limited	04.11.2020	3	<ul><li>07.12.2020</li><li>09.06.2021</li><li>19.05.2022</li></ul>
22	Copperbelt	Kitwe	Progress Hospital	07.02.2005	4	<ul><li>09.01.2020</li><li>02.06.2020</li><li>18.11.2020</li><li>16.02.2021</li></ul>
23	Copperbelt	Kitwe	Wusakile Mine Hospital		1	2020
24	Copperbelt	Kitwe	Evergreen Pharmacy	25.01.22	5	<ul> <li>22.07.2015</li> <li>09.09.2015</li> <li>11.02.2020</li> <li>09.12.2020</li> <li>15.09.2021</li> </ul>
25	Copperbelt	Chingola	Hope Land Health Shop	30.03.2021	1	3.2022
26	Copperbelt	Chingola	Stubbs Chemist	28.08.2019	1	6.2022
27	Copperbelt	Chingola	Brachi Pharmacy	12.06.2019	1	30.05.2020
28	Western	Mongu	Seraphim Health Shop	21.11.2019	2	• 02.03.2021 • 26.08.2021
29	Western	Mongu	Smart Pharmacy Limited	09.10.2018	7	<ul> <li>18.12.2018</li> <li>22.03.2018</li> <li>19.05.2020</li> <li>24.12.2020</li> <li>01.03.2020</li> <li>27.08.2021</li> <li>28.12.2021</li> </ul>
30	Western	Mongu	P & G Health Care	26.12.2018	4	• 19.05.2020 • 01.05.2021 • 27.08.2021 • 28.12.2021
31	Western	Mongu	Premium Care Pharmacy	12.02.2021	1	28.12.2021
32	Western	Mongu	Freshview Pharmacy	07.01.2021	1	28.12.2021
33	Western	Senanga	Mbuyoti Pharmacy	07.08.2015	1	30.06.2022
34	Western	Senanga	Ultimate Health Shop	24.06.2019	1	26.08.2021
35	Western	Kaoma	Lesa YeupaBumi Pharmacy	14.03.2018	1	22.12.2020

No.	Province	District	Facility	COR	Number of inspections	post licensing inspections
36	Western	Kaoma	Kaoma Pharmacy Limited	23.10.2017	5	<ul> <li>17.12.2018</li> <li>09.09.2019</li> <li>23.03.2021</li> <li>22.12.2020</li> <li>03.03.2021</li> </ul>
37	Western	Kaoma	Joyful Living Pharmacy Limited	04.09.17	1	14.06.2021
38	Central	Chibombo	Medilane Health Shop	29.12.2020	1	04.09.2021
39	Central	Kabwe	Five Star Pharmacy	03.11.2014	1	05.01.2022
40	Central	Kabwe	Broken Hill Chemist	15.03.2004	1	07.07.2022
41	Central	Kabwe	Kabwe pharmacy	02.10.2017	1	07.07.2022
42	Southern	Mazabuka	Mazabuka General Hospital		3	<ul><li>04.2018</li><li>07.2020</li><li>12.2021</li></ul>
43	Southern	Kazungula	Medicine World Pharmacy	31.08.2020	1	13.08.2020
44	Southern	Kazungula	Bekuchi Pharmacy	23.12.2020	1	12.2020
45	Southern	Livingstone	Noor Pharmaceuticals		3	• 18.01.2019 • 08.08.2019 • 25.08.2020
46	Southern	Livingstone	Livingstone Pharmacy	20.11.2018		
47	Eastern	Chipata	Chipata Chemist	6.11.2017	1	12.2021
48	Eastern	Chipata	Gondar Health Shop		1	24.01.2022
49	Copperbelt	Ndola	Hosea Chemist Pharmacy	26.09.2019	1	25.08.2021
50	Copperbelt	Ndola	Ads Pharmaceuticals	03.11.2021	1	9.2021
51	Copperbelt	Mufulira	Karibu Chemist		1	6.2022
52	Lusaka	Lusaka	Mylan Pharmaceuticals		3	• 02.2018 • 08.2019 • 11.2020
53	Lusaka	Lusaka	Pharmanova Limited		3	<ul><li>11.09.2019</li><li>02.07.2020</li><li>15.07.2021</li></ul>
54	Lusaka	Lusaka	Yash Life Sciences Limited			27 - 29.10.2021
55	Lusaka	Lusaka	Lusaka Pharmchem		2	• 14.09.2020 • 17.12.2021

No.	Province	District	Facility	COR	Number of inspections	post licensing inspections
56	Lusaka	Lusaka	Woodlands Chemist	18.11.2017	3	23.01.2013 20.01.2017 07.11.2017
57	Lusaka	Lusaka	Neclife Pharmacy	08.06.2021		
58	Lusaka	Lusaka	Link Pharmacy	10.02.2018	2	• 31.01.2020 • 31.07.2021

Appendix 11: ZAMRAs Presence in Regions in Comparison with Geographical Location and Man Power

Number of registered premises falling under the jurisdiction	Wholesale – 4 Retail – 170 Health shop – 76 *Public Hospital Pharmacy – 0 Private Hospital Pharmacy - 7	257 premises and 2 port of entries	Wholesale – 3 Retail – 24 Health shop – 28 *Public Hospital Pharmacy – 0 Private Hospital Pharmacy – 2	57 premises
Number of inspectors	5 inspectors (1 Principal Regulatory Officer; 2 Inspectors GDP and Access; 1 Inspector Investigations; 1 Assistant Inspector)	5 Inspectors	2 Inspectors i.e. 1 Inspector and 1 Assistant Inspector	2 Inspectors
List of Districts covered by sub region	<ul> <li>All Copperbelt districts (Kitwe, Ndola, Kalulushi, Chingola, Chillilabombwe, Mufulira, Luanshya, Lufwanyama, Mpongwe and Masaiti)</li> <li>KapiriMposhi</li> <li>Mkushi</li> <li>Serenje</li> <li>Luapula – (Chembe, Chiengi, Chipili, Kawambwa, Lungu, Mansa, Milenge, Mwansabombwe, Mwense, Nchelenge and Samfya)</li> <li>Muchinga districts – (Chama, Chinsali, Isoka, Mafinga, Mpika, Nakonde, Shiwangandu, Lavushimanda and Kanchibaya)</li> <li>Nakonde (port of entry)</li> <li>Simon Mwansa Kapwepwe (port of entry)</li> </ul>	AL	All districts in N.Western province     (Manyinga, Solwezi, Mwinilunga,     Kasempa, Kabompo, Mufumbwe, Zambezi,     Ikelenge and Chavuma)	AL
Sub-region		TOTAL	N. Western (Solwezi)	TOTAL
Region	Copperbelt - Ndola			
N/S	10			

Number of registered premises falling under the jurisdiction	Wholesale – 0 Retail – 11 Health shop – 11 *Public Hospital Pharmacy – 0 Private Hospital Pharmacy - 0	22 premises	Wholesale – 2 Retail – 36 Health shop – 14 Public Hospital Pharmacy – 2 Private Hospital Pharmacy – 0	54 premises	Wholesale – 135 Retail – 622 Health shop – 35 Public Hospital Pharmacy – 2 Private Hospital Pharmacy – 23	817 premises 2 port of entries
Number of inspectors	1 Inspector	1 inspector	3 i.e. 2 Acting Principal Regulatory Officers; 1 Assistant Inspector)	3 Inspectors	11 Inspectors' i.e. 1 Principal, 1 Investigations Inspector, 3 Inspectors GDP and Access, 4 Assistant Inspectors KKIA – 1 Inspector, Chirundu – 1 Assistant Inspector	11 Inspectors 2 Inspectors
List of Districts covered by sub region	All districts in Northern (Kasama, Chilubi, Kaputa, Luwingu, Mbala, Mporokoso, Mpulungu, Mungwi, Nsama, Lupososhi, Lunte, and Senga)	TOTAL	All districts in Eastern (Chadiza, Chasefu, Chipata, Katete, Kasenengwa, Lumezi, Lundazi, Lunsangazi, Mambwe, Nyimba, Petauke, Sinda, Vubwi, and Chipangali)	TOTAL	<ul> <li>All districts inLusaka – (Chilanga, Chongwe, Kafue, Luangwa, Lusaka and Rufunsa)</li> <li>Parts of central – Kabwe, Mumbwa, Itezhitezhi</li> <li>Southern - Siavonga, Chirundu border</li> <li>All districts in western (Kalabo, Kaoma, Limulunga, Luampa, Lukulu, Mitete, Mongu, Mulobezi, Mwandi, Nalolo, Nkeyema, Shangombo, Sikongo, Sioma)</li> <li>KKIA Port of entry</li> <li>Chirundu border</li> </ul>	TOTAL
Sub-region	Northern (Kasama) -	TO		TO		TO
Region			Eastern - Chipata		Lusaka –	
N/S			0.5		03	

Number of registered premises falling under the jurisdiction	Wholesale – 9 Retail – 53 Health shop – 8 Public Hospital Pharmacy – 3 Private Hospital Pharmacy – 2	75 premises 4 port of entries
Number of inspectors	2 inspectors i.e. 1 inspector; 1 assistant inspector	2 inspectors
List of Districts covered by sub region	All southern districts (Choma, Gwembe, Kalomo, Kazungula, Mazabuka, Monze, Namwala, Pemba, and Sinazongwe) Part of Western which include Sesheke, Senanga KatimaMulilo border, Kazungula port of entry Victoria Falls, Harry Mwaanga Nkumbula Airport	N.
Sub-region	southern	TOTAL
Region		
N/S		

Source: OAG Performance Data Analysis 2022

Note: \* meaning public hospitals not yet licensed with ZAMRA

Appendix 12: Field Inspection Findings on Registered Premises

	Adherance To Recom- mendations	N/A	Partial	N/A	N/A	N/A	N/A	N/A	N/A	Partial	NA	N/A	Partial	Partial	N/A	Partal	N/A	Partial	N/A	Fully
	Post Licensing Inspection By ZAMRA	2	Yes	2	2	2	2	2	2	Yes 22-10- 2019	2	o <sub>N</sub>	Yes - 28 -10-2020	Yes	2	Yes	N N	Yes	2	Yes
	Prescription Book	Not Updated	Not Updated	2	2	2	Yes	2	Yes	Yes - Not Updated	NA	2	Yes	Yes	Yes	Updated	Not Updated	Yes	, kes	W.A
	DDA	oN S	9	2	8	2	Yes	Yes	8	2	Yes	o N	2	2	2	Yes	Yes	2	Yes	Yes
	NDPSA	9	2	2	2	2	Yes	, kes	2	2	Yes	2	2	2	2	Yes	Yes	 &	, kes	Yes
	HPA N	2	2	2	2	2	Yes	Yes	2	2	2	2	2	2	2	Yes	Yes	2	Yes	Yes
	Health Shop Regulation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	NA A	N/A
	MASA	2	2	2	2	2	Yes	2	2	2	Yes	2	2	2	2	Yes	oN N	9	Yes	, kes
	STG	oN O	Yes	8	Š.	e S	Yes	2	2	Yes	Yes	Yes	Yes	8	Yes	Yes	No No	N <sub>S</sub>	2	Yes
	ZNF	2	2	2	2	2	Yes	ટ	Yes	ટ	Yes	ટ	ટ	2	2	Yes	No.	8	, kes	Yes
	Sops Available On Site	8	o N	8	8	8	Yes	8	Yes	Yes	Yes	8	§.	Yes	Yes	Yes	Yes	9 N	o N	Yes
	Dangerous Drug Register	Not Updated	2	2	2	2	Yes	Not Updated	Not Updated	9	Yes	Not Updated	Yes	Not Updated	Updated	Yes	Not Updated	o <sub>N</sub>	Yes	Yes
	Expired Drugs Register	Not Updated	Not Updated	2	2	2	Yes	Yes	Yes	Yes - Not Updated	Yes	Not Updated	Yes	Updated	Yes	Yes	No No	Yes	Yes	Yes
	Dangerous Drugs Cupboard	Secured	Secured	Not Secured	Not Secured	Not Secured	Secured	Secured	Not Secured	Not Secured	Secured	Secured	Secured	Not Secured	Secured	Secured	Secured	No DDA	Secured	Secured
	Expired Drugs Area	Yes NL	8	8	§.	§.	Yes	ક	2	Yes	Yes	2	yes	Yes	Yes	8	oN N	Yes	ક	Yes
	Running Water	o N	Yes	Yes	2	2	Xes	, kes	Yes	Yes	Yes	2	, kes	900g	Yes	Yes	Yes	Yes	Yes	, kes
	Updated Temp. Charts	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Not Updated	Update	Not Updated	Updated	Not Updated	Updated
	Thermometer Reading (Celsius)	23	20	19	No Thermometre	No Thermometre	23	23°	20°	33°	17°	21°	21°	18	70	19	11	22	24	23
	Ventilation	Good	Good	Poor	Poor	Poor	Good	Poog	Good	Good	Good	Poor	Good	Good	Good	Good	Good	Good	Good	Good
	Ceiling Condition	Poor Condition	Good	Good	Poor	Poor	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
	Presence Of Pharmadist (	Yes	8	2	, kes	2	8	Yes	8	Yes	Yes	Yes	oN N	Yes	Yes	Yes	Yes	Yes	Yes	9
	Valid HPCZ Practicing Licensing	Yes	Yes	Yes	g	શ	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	ZAMRA Registration	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Health Facility	Five Star Pharmacy	Happy Pill Pharmacy	Nimoz Pharmacy	Etiquette A Plus Pharmacy	Komi Community Pharmacy	Ruth Kaluluma Memorial Hospital	Healing Touch Pharmacy	Best Value Pharmacy	Downtown Pharmacy	Gatbro International Limited (Wholesale)	Live Health Pharmacy	Save Life Pharmacy	Southwest Pharmacy	Lusaka Health Care	We Care Pharmacy	Staywell Pharmacy	Jubilee Chemist	Karibu Chemist Limited	Lusaka Pharmaceutical Limited
	District	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka
	Province	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka
	No.	-	7	es es	4	2	9	~	ω	6	0	Ξ	5	5	4	15	16	17	85	19
- 1																				

Adherance To Recom- mendations	Partial	NA	Partial	Partial	N/A	Partial	Fully	Partial	Partial	Partial	N/A	Partial	Partial	N/A	N/A	Partial	Partial
Post Licensing Inspection By ZAMRA	Yes	8	Yes	Yes	8	Yes	Yes	Yes	Yes	Yes	8	Yes	Yes	N <sub>O</sub>	8	Yes	Yes
Prescription Book	Updated	O <sub>N</sub>	Not Updated	Yes	Yes	Not Updated	Yes	Yes	2	Yes	Yes	N/A	Yes	ON	Yes	Yes	Yes
DDA	Yes	0 <u>N</u>	S S	0 <u>N</u>	, kes	Yes	Yes	N/A	8	8	, kes	N N	§ N	0 N	o N	o N	Yes
NDPSA	Yes	2	Yes	2	Yes	Yes	Yes	N/A	2	2	Yes	o <sub>N</sub>	2	2	2	2	Yes
HPA	Yes	2	Yes	2	Yes	Yes	Yes	Yes	2	શ	Yes	No No	2	2	2	2	Yes
Health Shop Regulation	ΑN	N/A	N/A	N/A	¥/N	N/A	N/A	8	N/A	2	¥/N	N/A	N/A	N/A	N/A	N/A	N/A
MASA	Yes	8	Yes	8	Yes	Yes	Yes	Yes	8	8	Yes	o <sub>N</sub>	2	2	2	8	Yes
STG	S	2	ટ	2	Yes	Yes	Yes	Yes	ટ	ટ	Yes	8	2	ટ	2	2	Yes
ZNF	Yes	2	2	2	2	Yes	Yes	Yes	S.	S.	8	o <sub>N</sub>	2	2	2	2	Yes
Sops Available On Site	Yes	2	Yes	2	Yes	Yes	Yes	N/A	8	Yes	Yes	N N	2	2	2	8	Yes
Dangerous Drug Register	Yes	2	Yes	2	8	Yes	Yes	Ν/A	8	Yes	Yes	Yes	Yes	8	8	N N	Yes
Expired Drugs Register	Not Updated	N	Updated	NO	YES	Yes	Yes	Yes	N N	Yes	Yes	Yes	Yes	No	No	Yes	Yes
Dangerous Drugs Cupboard	Secured	8	Secured	Secured NL	Secured	Not Secured	Yes	ΝΆ	Yes	Yes	Yes	Yes	Yes	SA.	Yes	Yes	Yes
Expired Drugs Area	Yes	2	2	2	Yes	Yes	Yes	Yes	2	Yes	Yes	Yes	Yes	2	Yes	Yes	Yes
Running Water	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Updated Temp. Charts	Updated	o N	Not Updated	Not Updated	Updated	Not Updated	Not Updated	Not Updated	2	2	Yes	Not Updated	Yes	N <sub>O</sub>	2	8	Yes
Thermometer Reading (Celsius)	21	ω	70	23	78	92	75	, yes	8	Yes	23	24	21	80	9	23	18
Ventilation	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
Ceiling Condition	Poo 9	Good	Poo 9	Good	Poo9	Good	poo9	Good	Poor	poog	Poo9	Good	Poog	Good	Good	Poog	Good
Presence Of Pharmacist	Yes	08	Yes	o <sub>N</sub>	Yes	Yes	Yes	N/A	Yes	o N	Yes	No.	Yes	o V	Yes	oN N	Yes
Valid HPCZ Pacticing Licensing	Yes	Yes	Yes	2	Yes	Yes	Yes	, kes	Yes	Yes	Yes	Yes	Yes	, kes	Yes	Yes	Yes
ZAMRA Registration	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Health Facility	Agrimac Pharmacy	Ryino Pharmaceuticals	M. Care Pharmacy	The Things Pharmacy/Thabo	Mavlo Pharmacy	Kandende Pharmacy And Cosmetic Limited	Chirundu Pharmacy	Skyline Best Health Care - Health Shop	Welvis Pharmacy	Green Shop Pharmacy	Mary Begg Hospital	MpharmaLimited	AB Pharmacy	Ryino Pharmaceuticals	Day Break Pharmacy	Mas Health Shop	Charikam Pharmacy Limited
District	Lusaka	Ndola	Lusaka	Kafue	Kafue	Chirundu	Chirundu	Chirundu	Ndola	Ndola	Ndola	Ndola	Ndola	Ndola	Ndola	Ndola	Ndola
Province	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Southern	Southern	Southern	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt
O	50	21	72	8	24	52	92	27	88	53	8	34	33	æ	28	35	98

Adherance To Recom- mendations	N/A	Fully	Partial	Partial	Partial	Partial	Partial	Partial	Partial	Partial	N/A	Partial	Partial	Partial	Partial	Partial	Partial
Post A Licensing T I Inspection m Ey ZAMRA	<u> </u>	2	Yes	Yes	, kes	Yes	Yes	Yes	Yes	Yes	2	Yes	Yes	Yes	, kes	Yes	Yes
Prescription L Book L	 8	, kes	Yes	Yes	, kes	Yes	Yes	yes	Yes	Yes	Yes	Yes	Yess	Yes	, kes	Yes	Yes
DDA	2	Secured	2	2	Yes	Yes	2	N/A	8	, kes	N/A	N/A	9	, kes	Yes	, kes	2
NDPSA	Ŷ.	Yes	2	2	8	Yes	2	¥ X	2	Yes	N/A	N/A	8	Yes	Yes	Yes	8
HPA	₽	Yes	2	2	2	Yes	2	, se	2	, kes	, kes	Yes	2	, se	Yes	, kes	2
Health Shop Regulation	8	N/A	N/A	N/A	N/A	N/A	N/A	, kes	N/A	N/A	, kes	, Kes	N/A	N/A	N/A	N/A	N/A
MASA	2	Yes	2	2	2	Yes	2	Yes	2	Yes	Yes	Yes	2	Yes	Yes	Yes	2
STG	8	88,	°S	2	8	Yes	Yes	Yes	S <sub>S</sub>	§.	Yes	, ke	8	Yes	8	Yes	9
ZNF	8	Yes	8	Yes	8	Yes	£	Yes	8	2	8	Yes	8	Yes	Yes	Yes	2
Sops Available On Site	N/A	Yes	Yes	9	Yes	Yes	Yes	N/A	oN.	8	N/A	Yes	0 N	Yes	Yes	Yes	ON.
Dangerous Drug Register	N/A	Yes	Yes	Yes	Yes	Yes	Yes	N/A	Updated	2	N/A	N/A	Yes	2	Not Updated	Yes	Updated
Expired Drugs Register	Yes	, kes	Yes	Yes	Yes	Yes	Yes	S.	Updated	Updated	Yes	Yes	Not Updated	§.	Not Updated	Yes	Not Updated
Dangerous Drugs Cupboard	N/A	Secured	Secured	Not Secure	Not Secure	Yes	Not Secure	N/A	Secure	Secure	A/N	N/A	Not Secure	Secure	Not Secure	Secure	Secure
Expired Drugs Area	Yes	Yes	Yes	8	8	Yes	Yes	Yes	No.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Running Water	Yes	Yes	Yes	Yes	Yes	Yes	Yes	yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	yes	Yes
Updated Temp. Charts	Yes	Updated	Yes	2	/es	Yes	Yes	Not Updated	Not Updated	Updated	Updated	Not Updated	Not Updated	Not Updated	Not Updated	Updated	Not Updated
Thermometer Reading (Celsius)	20	24.9	2	32	23	56	56	83	70	23	16	Yes	22	23	19	27	25
Ventilation	Good	Good	Good	go og	Good	Good	Good	Good	Good	Good	Good	poog	goog	Good	Good	Good	Good
Ceiling Condition	Good	Good	Yes	900g	Good	Good	Good	Good	Good	Good	Good	Good	Good	Poor	Poor	Good	Good
Presence Of Pharmacist	ON N	Yes	2	2	Yes	Yes	8	2	Yes	2	8	2	9	, kes	Yes	8	2
Valid HPCZ Practicing Licensing	Yes	Yes	Yes	o <sub>N</sub>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
ZAMRA Registration	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Health Facility	Gift Health Shop	Wusakile Mine Hospital	Mik Med Pharmacy Limited	Joy Of Life Pharmacy	Chimwemwe Medicare Pharmacy Limited	Progress Hospital	Evergreen Pharmacy	Hope Land Health Shop	Stubbs Chemist	Brachi Pharmacy	Better Life Health Shop	Seraphim Health Shop	Smart Pharmacy Limited	P &G Health Care	Premium Care Pharmacy	Freshview Pharmacy	Mbuyoti Pharmacy
District	Ndola	Kitwe	Kitwe	Kitwe	Kitwe	Kitwe	Kitwe	Chingola	Chingola	Chingola	Chingola	Mongu	Mongu	Mongu	Mongu	Mongu	Senanga
Province	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Westem	Westem	Western	Western	Western	Westem
No.	37	88	39	40	14	42	43	44	45	46	47	84	49	20	15	25	23
		L	1		1						1				1		

											,						
Column   C	Adherance To Recom- mendations	Partial	Partial	Partial	Partial	N/A	N/A	Partial	N/A	Partial	Partial	Partial	Partial	Fully	Partial	Fully	N/A
Column   C	Post Licensing Inspection By ZAMRA	Yes	Yes	Yes	Yes	8	§.	Yes	2	Yes	Yes	8	Yes	Yes	Yes	Yes	8
Note	Prescription Book	Yes	N N	Yes	Not Updated	Not Updated	o <sub>N</sub>	Yes	Yes	Yes	Yes	o <sub>N</sub>	Yes	Yes	Yes	Yes	o <sub>N</sub>
Notice   Sample   Control   Contro		N/A	8	Yes	2	2	N/A	N/A	Yes	Yes	Yes	N/A	Yes	Yes	Yes	Yes	2
National   Control   Con	NDPSA	N/A	No No	Yes	S S	o N	N/A	N/A	S S	Š	Yes	N/A	N N	Yes	Yes	Yes	o <sub>N</sub>
Note   Court   Court	НРА	S	o <sub>N</sub>	ХөХ	Š	2	2	Yes	Yes	, kes	2	Yes	Yes	Yes	Yes	Yes	2
Number   Section   Secti	Health Shop Regulation	Yes	N/A	N/A	N/A	N/A	§.	Yes	N/A	N/A	N/A	Yes	N/A	N/A	N/A	N/A	N/A
Notes:   Commiss   Commi	MASA	Yes	No	Yes	N <sub>O</sub>	No No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	N <sub>O</sub>
	STG	ક	8	Yes	2	Yes	S	8	Yes	8	, se	, Ke	Yes	Yes	Yes	se,	2
Weight   Control   Contr		8	Yes	Yes	Yes	8	8	ક	Yes	ક	Yes	Yes	2	Yes	, kes	8	Š.
Noted		N/A	8	2	2	8	8	Yes	Yes	Yes	°S	o N	Yes	Yes	2	Yes	Yes
Poweron         Commission         State of power of	Dangerous Drug Register	ΝΆ	Yes	YES	Yes	N N	N/A	N/A	N N	Not Updated	Updated	N/A	Yes	ON	Yes	Yes	N
Weekern         Schools         Weekern         Schools         Weekern         Control         Control <t< th=""><th>Expired Drugs Register</th><th>Not Updated</th><th>Yes</th><th>Yes</th><th>Not Updated</th><th>Updated</th><th>9</th><th>9</th><th>Updated</th><th>Not Updated</th><th>Updated</th><th>Yes</th><th>Yes</th><th>Yes</th><th>Yes</th><th>Yes</th><th><u>8</u></th></t<>	Expired Drugs Register	Not Updated	Yes	Yes	Not Updated	Updated	9	9	Updated	Not Updated	Updated	Yes	Yes	Yes	Yes	Yes	<u>8</u>
Without States         Water States         Water States         Water States         Control of Control o	Dangerous Drugs Cupboard	N/A	Secure	Secure	Secure	Secure	N/A	N/A	Seare	Secured	Secured	N/A	Secures	Not Secured	Secured	Secured	Secured
Political Political Manual Figurity         Justificação Political Manual Figurity         Justificação Political P	Expired Drugs Area	Yes	Yes	Уes	yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes NI	Yes L	Yes NI	Yes NI
Proporter         Disect         Health Foolty         Zodana, Proporter         Vest         NA         Cood         Condition         Themson Reservation           Weetern         Koloma         Limited         Month Living         Yes         NA         Good         Cood         2.0           Weetern         Koloma         Limited         Yes         NA         Good         Good         2.0           Weetern         Koloma         Month Living         Yes         No         No         Good         Good         2.0           Central         Chibombo         Big Charc         Yes         Yes         No         Good         Yes         No           Central         Chibombo         Shing Pharmacy         Yes         Yes         No         Good         Good         2.2           Central         Chibombo         Shing Pharmacy         Yes         Yes         No         Good         Yes         Yes           Central         Koloma         Month Hammacy         Yes         Yes         No         Good         Good         Good         2.2           Central         Koloma         Month Hammacy         Yes         Yes         Yes         Yes         Yes	Running Water	Yes	Yes	Yes	, kes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Western         Springer         Control         Condition         Condition         Condition         Average         Condition         Condition         Average         Condition         Average         Condition         Condition         Condition         Average         Condition         Condition </th <th>Updated Temp. Charts</th> <th>Not Updated</th> <th>Not Updated</th> <th>Updated</th> <th>Not Updated</th> <th>Updated</th> <th>Not Updated</th> <th>Not Updated</th> <th>Updated</th> <th>Not Updated</th> <th>Not Updated</th> <th>Not Updated</th> <th>Updated</th> <th>Updated Temp.</th> <th>Updated Temp.</th> <th>Updated Temp.</th> <th>Not Updated</th>	Updated Temp. Charts	Not Updated	Not Updated	Updated	Not Updated	Updated	Not Updated	Not Updated	Updated	Not Updated	Not Updated	Not Updated	Updated	Updated Temp.	Updated Temp.	Updated Temp.	Not Updated
Province         Dates         Hearth Facility         Againston         Limited Health Present Pre	Thermometer Reading (Celsius)	Yes	21	20	22	19	N N	Yes	15	22	22	Yes	23	26	28	28	34
Provinces         District         Hearth Featty         ZAMISA, Registration Learning         Vision Hearth Featty Registration         ZAMISA, Prediction         Vision Premiser         Presence of Learning Premisery         Vision Premiser         Vision P	Ventilation	Good	Good	Good	Good	Poor	Yes	Yes	Good	Good	Good	Good	Good	Poor	900g	Average	Poor
Province         District         Health Facility         ZMARAL Shop         Ves         Ves           Western         Kaoma         Less Yeupaßumi         Yes         Yes           Western         Kaoma         Less Yeupaßumi         Yes         Yes           Western         Kaoma         Less Yeupaßumi         Yes         Yes           Western         Kaoma         Mamu Pharmacy         Yes         Yes           Central         Chibombo         Bag Chamz         Yes         Yes           Central         Chibombo         Spring Pharmacy         Yes         Yes           Central         Chibombo         Spring Pharmacy         Yes         Yes           Central         Kabwe         Pharmacy         Yes         Yes           Central         Kabwe         Broken Hill         Yes         Yes           Southern         Belactri         Yes         Yes           Southern         Broken Hill         <	Ceiling	Good	Poor	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
Province         District         Health Facility         ZAMRA Registration           Western         Senanga         Ultimate Health Shamacy         Yes           Western         Kaoma         Less Yeupabuni Pharmacy         Yes           Western         Kaoma         Limited Limited         Yes           Western         Kaoma         Big Charrz Limited         Yes           Central         Chibombo         Spring Pharmacy         Yes           Central         Chibombo         Spring Pharmacy         Yes           Central         Kabwe         Five Ster Pharmacy         Yes           Central         Kabwe         Five Ster Pharmacy         Yes           Southern         Mazzbuka         Yes           Southern         Medicine World Pharmacy         Yes           Southern         Nico Menorial Pharmacy         Yes	Presence Of Pharmacist	ΝΆ	N N	2	Yes	8	S.	8	2	8	Yes	8	Yes	Yes	Yes	Yes	8
Province         Destrict         Heasth Facility           Western         Senanga         Ultimate Heath           Western         Kaoma         Less YeupaBuni           Western         Kaoma         Less YeupaBuni           Western         Kaoma         Less YeupaBuni           Western         Kaoma         Limited           Western         Kaoma         Mamu Pharmacy           Limited         Limited           Central         Chibombo         Spring Pharmacy           Central         Kabwe         Spring Pharmacy           Central         Kabwe         Five Star           Central         Kabwe         Broken Hill           Southern         Medicine World           Southern         Medicine World           Pharmacy         Pharmacy	Valid HPCZ Practicing Licensing	Yes	Yes	o <sub>N</sub>	Yes	N <sub>O</sub>	Yes	N <sub>O</sub>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	O
Western Kaoma Western Kaoma Western Kaoma Western Kaoma Western Kaoma Central Chibombo Central Chibombo Central Kabwe Central Kabwe Southern Southern Southern Southern	ZAMRA Registration	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Western Western Western Western Central Central Central Central Southern Southern Southern	Health Facility	Ultimate Health Shop	Lesa YeupaBumi Pharmacy	Kaoma Phamacy Limited	Joyful Living Phamacy Limited	Mamu Pharmacy	Big Chamz Health Shop	Medilane Health Shop	Spring Pharmacy Limited	Five Star Pharmacy	Broken Hill Chemist	Davon Health Shop	KabwePharmacy	Mazabuka General Hospital	Medicine World Pharmacy	Bekuchi Pharmacy	Nico Memorial Clinic
	District	Senanga	Kaoma	Kaoma	Kaoma	Kaoma	Chibombo	Chibombo	Chibombo	Kabwe	Kabwe	Kabwe	Kabwe				
5     4     6     7     7     8     6     6     6     7     8     6     7     8     6     7     8     6     8     6     8     6     8     6     8     6     8     6     8     6     9     1     8     6     9     1 <th>Province</th> <th>Western</th> <th>Western</th> <th>Western</th> <th>Western</th> <th>Western</th> <th>Central</th> <th>Central</th> <th>Central</th> <th>Central</th> <th>Central</th> <th>Central</th> <th>Central</th> <th>Southern</th> <th>Southern</th> <th>Southern</th> <th>Southern</th>	Province	Western	Western	Western	Western	Western	Central	Central	Central	Central	Central	Central	Central	Southern	Southern	Southern	Southern
	NO.	귏	55	26	27	28	29	99	29	62	63	64	65	99	<i>L</i> 9	88	8

Adherance To Recom- mendations	Partial	Partial	N/A	Partial	Partial	NA	Partial	Partial	N/A	N/A	Partial	¥/N	Fully	Partial	Fully	Partial
Post Licensing Inspection By ZAMRA	Yes	Yes	2	Yes	Yes	8	Yes	Yes	9	9	Yes	2	Yes	Yes	Yes	Yes
Prescription Book	Yes	Yes	8	Yes	Yes	Yes	Yes	¥.N	2	Yes	, kes	Yes	N/A	N/A	N/A	Yes
DDA	Yes	Yes	2	Yes	Yes	Yes	° Z	°	°	Yes	Yes	N/A	Yes	Yes	Yes	Yes
NDPSA	Yes	Yes	2	Yes	Yes	Yes	8	2	2	Yes	Yes	Yes	Yes	Yes	, yes	Yes
HPA HPA	Yes	Yes	2	Yes	Yes	Yes	2	9	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Health Shop Regulation	ΝΆ	N/A	S.	N/A	2	N/A	N/A	N/A	N/A	8	N/A	2	N/A	ΝΆ	ĕ,	¥/N
MASA	Yes	Yes	2	, kes	Yes	Yes	, kes	2	2	Yes	Yes	Yes	, kes	Yes	Yes	Yes
STG	Yes	ક	ક	Xes	Yes	Yes	Yes	2	2	ક	Yes	ટ	N/A	N/A	Yes	Xes.
ZNF	Kes	2	2	, kes	2	Yes	ક	ટ	ટ	2	2	Yes	, Kes	Yes	ક	Kes
Sops Available On Site	Yes	N N	2	, kes	Yes	Yes	8	Yes	8	8	2	2	Yes	Yes	Yes	8
Dangerous Drug Register	Yes	Yes	2	YES	ΑΝ	Yes	Yes	Yes	Yes	8	Yes	8	N/A	YES	ÆS	YES
Expired Drugs Register	Yes	Yes	Ŷ.	YES	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Ŷ.	Yes	YES	YES	Yes
Dangerous Drugs Cupboard	Secured	Secured	N/A	Secured	N/A	Unsecured	Unsecured	Not Secured	Not Secured	N/A	Secured	N/A	Secured	Secured	Secured	Secured
Expired Drugs Area	Yes NI	Yes NI	2	Yes NI	Yes	Yes NI	Yes NI	Yes L	2	2	Yes NI	Yes NI	Yes L	Yes L	Yes L	Yes L
Running Water	Yes	Yes	Yes	Yes	Yes	Yes	8	Yes	Yes	9	Yes	Yes	Yes	Yes	Yes	Yes
Updated Temp. Charts	Not Updated	Not Updated	Not Updated	Updated Temp	Updated Temp	Not Updated	Not Updated	Updated Temp.	Updated Temp.	Not Updated	Updated Temp.	Not Updated	Updated Temp.	Updated Temp.	Updated Temp.	Updated Temp.
Thermometer Reading (Celsius)	78	23	78	23	28	73	33	78	27	99	28	Yes	22	28	20	28
Ventilation	Poor	Poor	Average	Good	Good	Poor	Poor	Good	Good	Good	Yes	Yes	Excellent	Good	Good	Good
Ceiling	Very Poor	Very Poor	Good	Poo9	Fair	Good	Poog	Good	Good	Very Poor	Good	Fair	Excellent	Bood	Good	Good
Presence Of Pharmacist	Yes	Yes	N <sub>O</sub>	Yes	N N	Yes	Yes	Yes	Yes	Yes	Yes	N N	Yes	Yes	Yes	Yes
Valid HPCZ Practicing Licensing	Yes	Yes. Not Displayed	No.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	2	Yes	Yes	Yes	Yes
ZAMRA Registration	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Health Facility	Noor Pharmaceuticals	Livingstone Pharmacy	Safeway Health Shop	Chipata Chemist	Gondar Health Shop	Ndola Teaching Hospital	Hosea Chemist Pharmacy	Ads Pharmaceuticals	Chemopharm Pharmacy	Bukari Health Shop	Karibu Chemist	LiwanzikaHealth Shop	Mylan Pharmaceuticals	Pharmanova Limited	Yash Life Sciences Limited	Lusaka Pharmchem
District					Chipata				Ndola	Ndola	Mufulira		Lusaka	Lusaka	Lusaka	Lusaka
Province	Southern	Southern	Southern	Eastern	Eastern	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Copperbelt	Lusaka	Lusaka	Lusaka	Lusaka
No.	02	12	72	73	47	75	9/	1	82	62	8	25	82	83	84	8

Adherance To Recom- mendations	Partial	Partial	Partial	N/A	N/A	N/A
Post Licensing Inspection By ZAMRA	Yes	Yes	Yes	8	N <sub>O</sub>	9
Prescription Book	Yes	Yes	Yes	Yes	Yes	N/A
DDA	oN N	9	Yes	Yes	Yes	Yes
NDPSA	oN N	o <sub>N</sub>	Yes	Yes	2	Yes
нРА	Yes	2	Yes	Yes	Yes	Yes
Health Shop Regulation	N/A	N/A	N/A	N/A	N/A	N/A
MASA	9	9	Yes	Yes	Yes	Yes
STG	Yes	Yes	No	Yes	Yes	N <sub>o</sub>
ZNF	Yes	Yes	Yes	2	Yes	Yes
Sops Available On Site	8	Yes	N N	8	N N	Yes
Dangerous Drug Register	ON	ON	YES	YES	YES	YES
Expired Drugs Register	YS	ON	Yes	ON	YES	YES
Dangerous Drugs Cupboard	Not Secured	Not Secured	Secured	Secure	Secure	Secure
Expired Drugs Area	Yes NI	N <sub>O</sub>	Yes NI	o <sub>N</sub>	Yes	Yes
Running Water	Yes	Yes	Yes	Yes	Yes	Yes
Updated Temp. Charts	Not Updated	Not Updated	Updated Temp.	Updated	Updated	Not
Thermometer Reading (Celsius)	30	28	24	23	24	24.5
Ventilation	Good	Good	Good	Good	Good	Good
Ceiling	Good	Good	Excellent	Good	Good	Good
Presence Of Pharmacist	Yes	SN.	Yes	8	Yes	Yes
Valid HPCZ Practicing Licensing	Yes	Yes	Yes	Yes	Yes	Yes
ZAMRA Registration	Yes	Yes	Yes	Yes	Yes	Yes
Health Facility	Woodlands Chemist	Neclife Pharmacy	Link Phamacy	Mums Care Hospital	Lusaka Trust Hospital	ZAMMSA
District	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka
Province	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka	Lusaka
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Appendix 13: Seizure Forms for Products sold in Unregistered Outlets

QUANTITY	191 bottles	4 bottles	4 bottles	4 bottles	2 bottles	1 bottle	3 bottles	4 bottles	4 bottles	2 bottles	5 bottles	_	4 bottles	4 bottles 2 bottles
EXPIRY DATE	05/2023	02/2024	07/2023	10/2024	04/2024	07/2023	07/2024	05/2024	05/2024	06/2024	08/2023		10/2024	10/2024
MFD.DATE	06/2020	03/2022	08/2021	11/2021	03/2021	08/2020	08/2021	12/2021	06/2022	07/2021	09/2020		11/2021	11/2021
BATCH NO.	0370497	DS-032207	PS161	281121	VM-24552	H 107-20	2108025	10212710	1070622	560721	OELO5243		491121	491121
MA NO.	075/033	200/028	149/001	104/005	106/048	155/007	134/053	093/040	077/017	518/003	002/004		518/004	518/004
MANUFACTURER	Shalina Lab. Pvt. Limited.	Galpha Laboratory	Leben	Yash Life Science Laboratories	Vigor Laboratories	International Drug Company	Aspen	Glenmark	Pharmanova (Z) Limited.	Yash Life Sciences	Ciron		Yash Life Sciences	Yash Life Sciences Yash Life Sciences
NAME OF PRODUCT	Betasol Lotion	Cefaloxin Suspension	Amoxicillian Suspension	Co-Trimocazole	Diarstop Suspension	Co-trimoxazole Suspension	Coldrid Syrup	Ascoril Expectorant	Novalyn Cough Expectorant	Trilyn (Gripe Water)	Cirogan (promethazine) syrup		Triphen (honey and ginger)	Triphen (honey and ginger) Triphen Expectorant
NAME OF PHARMACY	Phen Game	Unmarked Drug Store (Mkushi)					Unmarked Drug Store (Mkushi)				Unmarked Drug Store (Mkushi)			
Date of Seizure											12.7.2022			

Date of Seizure	NAME OF PHARMACY	NAME OF PRODUCT	MANUFACTURER	MA NO.	BATCH NO.	MFD.DATE	EXPIRY DATE	QUANTITY
12.7.2022	Just Shall live by Faith Drug Store	Shal' Artem 24	Shalina Laboratories Pvt Limited.	075/094	1372928	07/2021	06/2024	1x24x7 tablets
		Shal' Artem 6	Shalina Laboratories Pvt Limited.	075/093	1372439	06/2021	05/2024	7x6x1 tablets
		Shalcip 500	Shalina Laboratories Pvt Limited.	075/050	0370391	05/2020	04/2023	6x10 tablets
		Kirafu 50	Shalina Laboratories Pvt Limited.	075/041	0373759	12/2020	11/2023	1x4x5 tablets
13.7.2022	Green World Herbal Clinic (LUANO MARKET)	Lonart Tablets	Bliss GVs	1031204	B3AAG013	01/2022	12/2024	1,264 tablets
		Tetravard 1% eye ointment	Vigar Laboratories	160/058	TV -02	10/2021	09/2024	16 TUBES
		Uprone -20 omeprazile 20 mg	Bliss GVs	254/070	DUC004	06/2021	05/2024	4X10 tablets
		Shalcip-500	Shalina	072/050	1374651	12/2001	11/2024	6x10 tablets
		Azithromycin tablet 500 mg	Leban Laboratories Limited	149/090	T921	06/2021	05/2023	3x3 tablets
		Amoxycillin Oral Solution	SparshBioTechLimited.	231/005	X0972	02/2021	01/2021	4 bottles
		Metro 200 tablets	Vigar Laboratories	160/017	T20217	05/2022	04/2025	19X10 bottles
		Nystalin Suspension	Leben	149/048	L2461	01/2022	12/2023	4 bottles
13.7.2022	Mansansa Drug Store (NOLA)	Stalfin (sulfadoxine&Pyrimethane)	Stallion Laboratories	016/006	Z-41	11/2020	11/2022	20X 3 tablets
		Stalfin (sulfadoxine&Pyrimethane)	Stallion Laboratories	016/006	Z-41	11/2020	11/2022	30 x3 tablets

QUANTITY	4 X100 ML	27x10 tablets	4X100ML	4X24 tablets	11X4 tablets	20 X 10 tablets	3 x100 ml	17 x10 tablets	3 x 1G Vials	3 bottles	6 bottles.	9 x 24 tablets	5 x 30 ml bottles	10 X10 tablets	10 X 10
EXPIRY DATE	12/2022 4	02/2025 27	06/2024 43	04/2024 43	01/2025	07/2024 20 tal	08/2024 3 3	09/2022	04/2022 3 3	08/2023 3 1	02/2022 61	11/2023	07/2022 5 bo	$05/2021 \qquad 10$	06/2021
MFD.DATE	01/2020	03/2022	07/2021	05/2021	02/2022   0	10/2021	08/2021	10/2020	05/2019	09/2020	03/2020	12/2020	08/2019	06/2018	07/2018
BATCH NO.	CS 017	003279	VM-25565	KLR 037	T 2027	LT-248	1129	037225	P9e11	130920	F3969	0373431	5806772	K893	JM 59
MA NO.	271/010	286/002	160/048	245/013	098/032	245/005	188/016	075/057	075/083	104/002	149/046P	075/094	283/021	126/038	022/008
MANUFACTURER	Cameo Health Care (I) Pvt Limited.	Africure Pharmaceuticals	Vigor Laboratories	Bliss GVs Pharma LIMITED.	Kamal International	Bliss GVs Pharma Limited	Elys Chemical Industries limited	Shalina	Shalina Healthcare	Yash Life Sciences Limited	Leben Laboratories Limited	Shalina	Universal Corporation Limited	Tabs Flaming Pharma	JMB Pharma
NAME OF PRODUCT	Co-Trimoxalole suspension	Metrosim-200	Diarstop Suspension	Lornat tablets	7 hours (Sildenafil 50mg)	Lofnac 100	Elymox (Amoxicillin) Oral Suspension	Cevite Vit C Tablet	Cetriaxone Inj.	Triphen Expectorant	Elcuf Cough Syrup	Shal' Artem	Nyastatin Oral Drops	Walidixic Acid 500mg	Furosemide 40mg Tablets
NAME OF PHARMACY								Luapula Pharmacy (MANSA)	Broadway Chemist (NDOLA)					Samuel Z Health (KapiriMposhi)	
Date of Seizure								8.12.2022	14.5.2022						

	12/2019       11/2022       5 X 200 MIs         02/2019       01/2021       5 X 10         01/2020       Capsules         12/2022       22 X 10         Tablets	11/2022 01/2021 12/2022 05/08/ 2022	11/2022 01/2021 12/2022 05/08/ 2022 11/2023	11/2022 01/2021 12/2022 05/08/ 2022 11/2023 09/2023	11/2022 01/2021 12/2022 05/08/ 2022 11/2023 09/2023	11/2022 01/2021 12/2022 05/08/ 2022 11/2023 09/2023	11/2022 01/2021 12/2022 05/08/ 2022 11/2023 09/2023 02/08/21 12/2021	11/2022 01/2021 12/2022 05/08/ 2022 11/2023 09/2023 02/08/21 12/2021 10/2021	11/2022 01/2021 12/2022 05/08/ 2022 11/2023 09/2023 09/2023 12/2021 10/2021 06/2021	11/2022 01/2021 12/2022 05/08/ 2022 11/2023 09/2023 09/2023 10/2021 10/2021 06/2021 01/2022	11/2022 01/2021 12/2022 05/08/ 11/2023 09/2023 09/2023 12/2021 10/2021 06/2021 01/2022
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075/065 G	177/001 F7 075/049 P.				<u>e</u>	۵.	<u>e</u> ,	<u>e</u> ,	<u> </u>	Д.	<u>e</u>
Shalina	Fourrts Shalina	Fourrts Shalina 60 mg Fosun Pharma	Fourits Shalina 60 mg Fosun Pharma KausikhTherapeitics Rliss GVS Pharma	Fourrts Shalina 60 mg Fosun Pharma KausikhTherapeitics Bliss GVS Pharma Limited.	Fourrts Shalina 60 mg Fosun Pharma KausikhTherapeitics Bliss GVS Pharma Limited. Meyer Organics	Fourrts Shalina 60 mg Fosun Pharma KausikhTherapeitics Bliss GVS Pharma Limited. Meyer Organics Emcure Pharma	Fourrts Shalina 60 mg Fosun Pharma KausikhTherapeitics Bliss GVS Pharma Limited. Meyer Organics Emcure Pharma	Fourrts Shalina 60 mg Fosun Pharma KausikhTherapeitics Bliss GVS Pharma Limited. Meyer Organics Emcure Pharma Hope Pharmaceutical Medley Pharma	Fourrts Shalina 60 mg Fosun Pharma KausikhTherapeitics Bliss GVS Pharma Limited. Meyer Organics Emcure Pharma Hope Pharmaceutical Medley Pharma	Fourrts Shalina 60 mg Fosun Pharma KausikhTherapeitics Bliss GVS Pharma Limited. Meyer Organics Emcure Pharma Hope Pharmaceutical Medley Pharma Bliss GVs Pharma	Fourrts Shalina 60 mg Fosun Pharma KausikhTherapeitics Bliss GVS Pharma Limited. Meyer Organics Emcure Pharma Hope Pharma Bliss GVs Pharma ShelysPharmceuticals ShelysPharmceuticals
Super Apeti plus syrup Sha	Omeprazole (OMFIL 20) Fou Cyroheptadine (super apeti) Sha tablets	tti)	rti)	(ij)	ti)	rti)	ti)	ti)	ij) iji	m m	m m
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Date of Seizure	NAME OF PHARMACY	NAME OF PRODUCT	MANUFACTURER	MA NO.	BATCH NO.	MFD.DATE	EXPIRY DATE	QUANTITY
		Phenoxymethyl	Milan Laboratories Pvt Limited.	280/015	MP19476	11/2019	10/2021	100 mls x 5 bottles
		Lonart Tablets	Bliss GVs Pharma Limited.	245/013	KLR019	05/2020	04/2023	3X8X7 tablets
27 .12. 2019	Shop No.8, Buchi, (Kamitondo Market)	Lonart 20/120 Suspension	Bliss GVs Pharma Limited.	245/015	H1ALM105	11/2018	10/2020	
		Hycorum Cream 15mg	Laboratory & Allied Limited	309/002	B74975	07/19	06/22	
		Ketazol 30g	ShalinaLaboartories	075/024	95089	05/18	04/21	
		Ceterizine Tablet	Medley Pharmaceuticals	106/020	14178	12/2018	11/2021	
		Griseofulvin 500 mg	Leben Laboratories	149/060	14178	12/2018	11/2021	
10 .11. 2020	Patking Drug Store (Chililabombwe)	Metronidazole Tab 200mg	JMB Pharma Limited.	022/005	J-15	12/2019	11/2022	200 tablets
		Omeprazole 20mg tabets	Bliss GVS Limited.	254/070	UNC016	01/2020	12/2022	100 tablets
		Lumeter tablets	Macleods	12/729	NAA2048A	03/2020	02/2023	30 x 18 tablets
31.1.2020	Health Shop (Kakoso Level 1 hospital)	Amoxillian 250mg cap	NCPCL	033/003	1904024	04/19	04/23	6x100 caps + 1 x 60 cap
		Metrozinidazole tablets	JMB	022/005	JM-23	03/19	02/22	4 x 100 tablets
		Amoxicillin suspension	LEBEN	149/001	BS 89	05/2019	04/2021	1 x 6 bottles
		Amoxicillin suspension	ELYS	188/016	9F137	06/19	05/22	9 bottles

Date of Seizure	NAME OF PHARMACY	NAME OF PRODUCT	MANUFACTURER	MA NO.	BATCH NO.	MFD.DATE	EXPIRY DATE	QUANTITY
Seizure date	Name of Pharmaceutical establishment	Name of product	Manufacturer	MA. No.	Batch No.	Mfd Date	Expiry Date	Quantity
12.07.22	Gluccs Health Shop – (Mkushi)	Lofnac 100mg tablets	Bliss GVS Pharma	245/005	TC 332	11/2021	10/2024	20 x 10 x 2 tablets
		Stopcold tablets	Vigor	160/014	TO68153	02/2022	01/2025	46 x 4 tablets
		Cloxacillin Suspension	Galpha Laboratories	200/025	Ds-012203	01/2022	12/2023	2 x 100 mls
		Kemoxyl 250mg	Laboratory ad allied Limited	309/007	80693	02/2022	01/2025	21 x 10 capsules
		Assorted medicines						One sack
		Aminophylline 100mg tablets	Glumex	169/024	Amp 2102	06/2021	05/2021	100 x 40 tablets
		Delased 100mls cough syrup	Regal Pharmacy	205/001	210710	03/2021	02/2024	6 bottles
		Shal, Artem	Shalina	075/094	1372928	07/2021	06/2024	5 x 24 bottles
		Omeshal 10 capsules	Shalina	075/059	2371747	03/2022	02/2025	3 x 100 capsules
		Atenolo Tablets	Macleods	HAK2100IA		09/2021	08/2023	7 x 14 tablets
		Powerful 100mg (sildenad)	Vigor Laboratories	160/071	Vm - 05544	02/2021	01/2024	6 sachets
		Amitriphylline 25mg	Leben	ı	T1060	06/2020	05/2023	90 tablets

Date of Seizure	NAME OF PHARMACY	NAME OF PRODUCT	MANUFACTURER	MA NO.	BATCH NO.	MFD.DATE	EXPIRY DATE	QUANTITY
		Coldrid tablets	Medley Pharmacy	108/057	D20059	02/2022	01/2026	9 x 9 tablets
		Mucolyn	Beta Health care Int	134/046	2203076	03/2022	02/2025	2
		Ibucap	Shalina	075/032	1372469	06/2021	05/2024	17 x 10 capsules
12.07.2022	Chitowela Drug Store – (Mkushi)	Cefalexin Oral susp	Sun Pharmaceuticals Limited	112/071	DFD 00048	01/2022	12/2023	4 x 100 mls
		Erythromycin oral susp	Aurochem Laboatories Limited	178/016	E138	05/2021	04/2024	5 x 100 mls
		Amoxcillin oral susp	Galpha Laboratories Limited	200/008	GXD 2100064	12/2021	11/2024	5 x 100 mls
		Nystatin oral drops	Universal corporation Limited	283/021	5808289	09/2020	08/2023	4 x 30mls
		Hydrocortisone cream 1%	Laboratory and drug Limited	309/002	B78630	04/2021	03/2024	8 x 15g tubes
		Comit - 50	Bliss GVs Pharma Limited	245/004	KCT 006	04/2021	03/2024	16 x 4 tablets
		Kifaru 50	Shalina laboratories Limited	075/041	0373758	12/2020	11/2023	16 x 4 tablets
		Agycin - 500	Bliss Gvs Pharma Limited	254/055	AGT 011	06/2021	05/2024	20 x 3 tablets
		Funbact - A	Bliss Gvs Pharma Limited	245/003	FTS 015	05/2021	04/2024	8 x 30g tubes
		Sulfatrim (co trimoxdole susp)	Shalina laboratories Limited	00/5/00	1130206	03/2021	02/2024	5 x 100 mls
12.07.2022	Unmarked Drug store (new market – Mkushi)	Lonart Tablets	Bliss GVS phrmaLimited	245/013	A3AA6007	07/2021	06/2024	5 x 18 tablets
		Agycin 500	Bliss GVS phrmaLimited	254/055	AGT015	08/2021	07/2024	5 x 3 tablets

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Date of Seizure	NAME OF PHARMACY	NAME OF PRODUCT	MANUFACTURER	MA NO.	BATCH NO.	MFD.DATE	EXPIRY DATE	QUANTITY
		Paludoxio	Bliss GVS phrmaLimited	245/021	KPL002	02/2021	01/2024	10 x 3 tablets
		Cadiphen cough syrup	Cadilapharmaceiticals Limited	ı	W66E1015	07/2021	06/2025	3 x 100 mls
		Bigmet (metformin)	Bliss GVS phrmaLimited	245/027	KBT 011	11/2021	10/2024	10 x 10 tablets
12.07.2022	Twiza Drug store (nwmkt,town centre Mkushi)	Cefalexin susp	Sun pharma	112/071	DFD0004B	01/2022	12/2023	5 boxes
		Erythromycin susp	DAWA	ı	2001112	09/2020	12/2022	5 boxes
		Amoxicillin susp	Elys chemicals	188/016	0233	12/2020	11/2023	4 boxes
		Cloxacillin susp	Galpha laboratories	200/025	DS-012203	07/2022	12/2023	7 boxes
		Lonart tablets	Bliss GVS pharma Limited	245/013	A3AAG007	07/2021	06/2024	2 x (10 x 3 x 8) tablets
		Omeprazole capules	Bliss GVS pharma Limited	245/070	DUC002	06/2021	05/2024	17 x 10 capsules
		Cadiphen	Cadila pharmaceuticals	I	N66E1015	07/2021	06/2025	7 bottle
		Triphen Expectorant	Yash life Sciences	104/002	300522	05/2022	04/2025	5 bottles
		Cloxacillin oral 501	Leben	149/043	I	12/2021	11/2023	1 bottle
		Kifarm 100 (sildenafil)	Shalina	075/087	1374881	12/2021	11/2024	14 x 4 bottles
		Triphen wet cough	Yash life sciences	481/012	470621	06/2021	05/2024	5 bottles
	-	-	_					

QUANTITY	63 products	6 x 7 tablets	11 x 18 tables	6 x 7 tablets	11 x 18 tablets	2 x 100 mls	19 x 10 capsules	3 x 100 tablets	8X100 Tablets	470 Tablets	4x100 Tablets	420 Tablets	200 tablets	80 Tablets	210 Tablets
EXPIRY DATE		05/2024	12/2024	05/2024	12/2024	02/2024	08/2024	05/2025	10/2022	12/2022	01/08/21	07/2022	11/2022	09/2022	11/2022
MFD.DATE		06/2021	01/2022	06/2021	01/2022	03/2021	09/2021	03/2022	11/19	01/20	02/08/19	08/19	11/2018	10/2019	12/2019
BATCH NO.		1372439	B3AAG016	1372439	B3AAG016	1130206	PIC04	003281	JYAKF003	B54iG001B	198PQ03X	KE19157		MHET/1698	J-17
MA NO.		075/093	1	075/093	ı	002/000	960/\$20	286/007	254/027		019/010	007/027		087/002	022/016
MANUFACTURER		Sunlin laboratories Limited	Bliss GVS pharma Limited	Shalina laboratories Limited	Bliss GVS pharma Limited	Shalina laboratories Limited	Shalina laboratories Limited	Africure Pharmaceuticals Limited	Bliss GVs Pharma	Torrent Pharma	Meyer organics	Kausisk	UCPC International	Hope Pharmaceuticals	JMB Pharmaceuticals
NAME OF PRODUCT	Assorted medicines	Shrartem forte	Lonart tablets	Sulftrim oral suspension	Lonart tablets	Sulftrim oral susp	Amoxyl 250	Metrozim 200	BGMET ( Metformin)	Sodium Valproate	Omeprazole 20mg (Lomez)	Acycovir 200mg tablets	Preadasone 5 mg	Blue Strength (Sidenafil)	Ciprofloxacin Tabs 500 mg
NAME OF PHARMACY		Royd Nkhoma (Luanshya)							Bukari Health Shop (Ndola					Alsaly Health Shop (Chilalabombwe)	
Date of Seizure		27.06.2022												16.10.2022	

Date of Seizure	NAME OF PHARMACY	NAME OF PRODUCT	MANUFACTURER	MA NO.	BATCH NO.	MFD.DATE	EXPIRY DATE	QUANTITY
		BGMET (metformin) 500 mg	BLIS GVS Pharma	245/027	JIAKF005	11/2019	10/2022	200 Tablets
		Azithromycin 500 mg	BLIS GVS Pharma	245/027	JIAKF005	07/2019	06/2022	9 x 3 Tablets
		Sildenafil (Kifara-50)	Shalina		J9015	10/2019	09/2022	37 X 2 Tablets
		Fluconazole 200 mg	JMB Pharmaceutical		JC-2	07/2019	06/2022	21 X 10 Tablets
		Norethisterane 5 mg	Unicure		E18119005	11/2019	10/2022	33 x 10 Tablets
26.10.2020	Bukari Health Shop (Mpongwe)	Methyldopia 250 mg Tablets	Medopharma	272/024	9MD30	04/2019	03/2022	1046 Tablets
		Azithromyclin 5 ml Suspension	Leben	149/089	L3428	03/2019	02/2021	8 bottles
		Acetozslamide tabs.	BDH Industries Limited   199/031	199/031	06119	11/2019	10/2022	2 x 10 x 10 Tablets
		Cilibeclamide 5mg	Lincoln	228/009	696НН	04/2019	14/2022	380 Tablets

Appendix 14: Level of Adherence to the Authrority's Recommendations

	Province	District	Health Facility	ZAMRA Registration	Post Licensing Inspection By ZAMRA	AdheranceTo Recommendaations
1	Lusaka	Lusaka	George Health Centre	No	N/A	N/A
2	Lusaka	Lusaka	Five Star Pharmacy	Yes	No	N/A
3	Lusaka	Lusaka	Matero Main Health Centre	No	N/A	N/A
4	Lusaka	Lusaka	Materol Level 1 Hospital	No	N/A	N/A
5	Lusaka	Lusaka	Chipata Levell Hopsital	No	N/A	N/A
6	Lusaka	Lusaka	Happy Pill Pharmacy	Yes	Yes	Partial
7	Lusaka	Lusaka	Nimoz Pharmacy	Yes	No	N/A
8	Lusaka	Lusaka	Kanyama General Hospital	No	N/A	N/A
9	Lusaka	Lusaka	Etiquette A Plus Pharmacy	Yes	No	N/A
10	Lusaka	Lusaka	Komi Community Pharmacy	Yes	No	N/A
11	Lusaka	Lusaka	Ruth Kaluluma Memorial Hospital	Yes	No	N/A
12	Lusaka	Lusaka	Chawama General Hospital	No	N/A	N/A
13	Lusaka	Lusaka	Healing Touch Pharmacy	Yes	No	N/A
14	Lusaka	Lusaka	John Howard Health Post	No	N/A	N/A
15	Lusaka	Lusaka	Best Value Pharmacy	Yes	No	N/A
16	Lusaka	Lusaka	Downtown Pharmacy	Yes	Yes 22-10-2019	Partial
17	Lusaka	Lusaka	Gatbro International Limited (Wholesale)	Yes	No	N/A
18	Lusaka	Lusaka	Live Health Pharmacy	Yes	No	N/A
19	Lusaka	Lusaka	Kabwata Health Centre	No	N/A	N/A
20	Lusaka	Lusaka	Save Life Pharmacy	Yes	Yes - 28 -10- 2020	Partial
21	Lusaka	Lusaka	Chilenje Level 1 Hospital	No	N/A	N/A
22	Lusaka	Lusaka	State House Urban Health Centre	No	N/A	N/A
23	Lusaka	Lusaka	Railway Health Centre	No	N/A	N/A
24	Lusaka	Lusaka	Kamwala Health Centre	No	N/A	N/A
25	Lusaka	Lusaka	Southwest Pharmacy	Yes	Yes	Partial
26	Lusaka	Lusaka	Lusaka Health Care	Yes	No	N/A
27	Lusaka	Lusaka	We Care Pharmacy	Yes	Yes	Partal
28	Lusaka	Lusaka	Staywell Pharmacy	Yes	No	N/A
29	Lusaka	Lusaka	Jubilee Chemist	Yes	Yes	Partial
30	Lusaka	Lusaka	Karibu Chemist Limited	Yes	No	N/A

	Province	District	Health Facility	ZAMRA Registration	Post Licensing Inspection By ZAMRA	AdheranceTo Recommendaations
31	Lusaka	Lusaka	Lusaka Pharmaceutical Limited	Yes	Yes	Fully
32	Lusaka	Lusaka	UTH Adult Pharmacy	No	N/A	N/A
33	Lusaka	Lusaka	UTH Pediatrics. Hospital Pharmacy	No	N/A	N/A
34	Lusaka	Lusaka	Levy Mwanawasa Pharmacy	No	N/A	N/A
35	Lusaka	Lusaka	Mylan Pharmaceuticals	Yes	Yes	Fully
36	Lusaka	Lusaka	Pharmanova Limited	Yes	Yes	Partial
37	Lusaka	Lusaka	Yash Life Sciences Limited	Yes	Yes	Fully
38	Lusaka	Lusaka	Lusaka Pharmchem	Yes	Yes	Partial
39	Lusaka	Lusaka	Woodlands Chemist	Yes	Yes	Partial
40	Lusaka	Lusaka	Neclife Pharmacy	Yes	Yes	Partial
41	Lusaka	Lusaka	Link Pharmacy	Yes	Yes	Partial
42	Lusaka	Lusaka	Mums Care Hospital	Yes	No	N/A
43	Lusaka	Lusaka	Lusaka Trust Hospital	Yes	No	N/A
44	Lusaka	Lusaka	ZAMMSA	Yes	No	N/A
45	Lusaka	Lusaka	Chelstone Zonal Hospital	No	N/A	N/A
46	Lusaka	Lusaka	Chainda Health Centre	No	N/A	N/A
47	Lusaka	Lusaka	Agrimac Pharmacy	Yes	Yes	Partial
48	Lusaka	Lusaka	M. Care Pharmacy	Yes	Yes	Partial
49	Lusaka	Lusaka	Kalingalinga Health Centre	No	N/A	N/A
50	Lusaka	Kafue	The Things Pharmacy/ Thabo	Yes	Yes	Partial
51	Lusaka	Kafue	Kafue General Hospital	No	N/A	N/A
52	Lusaka	Kafue	Mavlo Pharmacy	Yes	No	N/A
53	Copperbelt	Ndola	Welvis Pharmacy	Yes	Yes	Partial
54	Copperbelt	Ndola	Green Shop Pharmacy	Yes	Yes	Partial
55	Copperbelt	Ndola	Mary Begg Hospital	Yes	No	N/A
56	Copperbelt	Ndola	MpharmaLimited	Yes	Yes	Partial
57	Copperbelt	Ndola	Masala Clinic	No	N/A	N/A
58	Copperbelt	Ndola	AB Pharmacy	Yes	Yes	Partial
59	Copperbelt	Ndola	Ryino Pharmaceuticals	Yes	No	N/A
60	Copperbelt	Ndola	Day Break Pharmacy	Yes	No	N/A

	Province	District	Health Facility	ZAMRA Registration	Post Licensing Inspection By ZAMRA	AdheranceTo Recommendaations
61	Copperbelt	Ndola	Mas Health Shop	Yes	Yes	Partial
62	Copperbelt	Luanshya	Copperbelt Regional Hub	No	N/A	N/A
63	Copperbelt	Ndola	Ndeke Mini Hospital	No	N/A	N/A
64	Copperbelt	Ndola	ChipokotaMayamba Clinic	No	N/A	N/A
65	Copperbelt	Ndola	Twapia Urban Health Centre	No	N/A	N/A
66	Copperbelt	Ndola	Lubuto Clinic	No	N/A	N/A
67	Copperbelt	Ndola	Auther Davison Hospital	No	N/A	N/A
68	Copperbelt	Ndola	Charikam Pharmacy Limited	Yes	Yes	Partial
69	Copperbelt	Ndola	Kawama Clinic	No	N/A	N/A
70	Copperbelt	Ndola	Gift Health Shop	Yes	No	N/A
71	Copperbelt	Ndola	Railway Surgery Clinic	No	N/A	N/A
72	Copperbelt	Kitwe	Ndeke Mini Hospital	No	N/A	N/A
73	Copperbelt	Kitwe	Riverside Clinic	No	N/A	N/A
74	Copperbelt	Kitwe	Kwacha Clinic	No	N/A	N/A
75	Copperbelt	Kitwe	Buchi Main Clinic	No	N/A	N/A
76	Copperbelt	Kitwe	Bulangililo Clinic	No	N/A	N/A
77	Copperbelt	Kitwe	Wusakile Mine Hospital	Yes	No	Fully
78	Copperbelt	Kitwe	Nkana East Health Centre	No	N/A	N/A
79	Copperbelt	Kitwe	Mik Med Pharmacy Limited	Yes	Yes	Partial
80	Copperbelt	Kitwe	Luangwa Urban Health Centre	No	N/A	N/A
81	Copperbelt	Kitwe	Mulenga Urban Health Centre	No	N/A	N/A
82	Copperbelt	Kitwe	Joy Of Life Pharmacy	Yes	Yes	Partial
83	Copperbelt	Kitwe	Chimwemwe Medicare Pharmacy Limited	Yes	Yes	Partial
84	Copperbelt	Kitwe	Progress Hospital	Yes	Yes	Partial

	Province	District	Health Facility	ZAMRA Registration	Post Licensing Inspection By ZAMRA	AdheranceTo Recommendaations
85	Copperbelt	Kitwe	Kitwe Teaching Hospital	No	N/A	N/A
86	Copperbelt	Kitwe	Evergreen Pharmacy	Yes	Yes	Partial
87	Copperbelt	Chingola	Chiwempala Clinic	No	N/A	N/A
88	Copperbelt	Chingola	Hope Land Health Shop	Yes	Yes	Partial
89	Copperbelt	Chingola	Kabundi East Clinic	No	N/A	N/A
90	Copperbelt	Chingola	Stubbs Chemist	Yes	Yes	Partial
91	Copperbelt	Chingola	Brachi Pharmacy	Yes	Yes	Partial
92	Copperbelt	Ndola	Ndola Teaching Hospital	Yes	No	N/A
93	Copperbelt	Ndola	Hosea Chemist Pharmacy	Yes	Yes	Partial
94	Copperbelt	Ndola	Ads Pharmaceuticals	Yes	Yes	Partial
95	Copperbelt	Ndola	Chemopharm Pharmacy	Yes	No	N/A
96	Copperbelt	Ndola	Bukari Health Shop	Yes	No	N/A
97	Copperbelt	Mufulira	Ronald Ross General Hospital	No	N/A	N/A
98	Copperbelt	Mufulira	Karibu Chemist	Yes	Yes	Partial
99	Copperbelt	Mufulira	LiwanzikaHealth Shop	Yes	No	N/A
100	Copperbelt	Chingola	Better Life Health Shop	Yes	No	N/A
101	Central	KapiriMposhi	TAZARA Clinic	No	N/A	N/A
102	Central	KapiriMposhi	KapiriMposhi District Hospital	No	N/A	N/A
103	Central	Chibombo	Chibombo Rural Health Centre	No	N/A	N/A
104	Central	Chibombo	Big Chamz Health Shop	Yes	No	N/A
105	Central	Chibombo	Medilane Health Shop	Yes	Yes	Partial
106	Central	Chibombo	Liteta District Hospital	No	N/A	N/A
107	Central	Chibombo	Spring Pharmacy Limited	Yes	No	N/A
108	Central	Kabwe	Five Star Pharmacy	Yes	Yes	Partial
109	Central	Kabwe	Broken Hill Chemist	Yes	Yes	Partial
110	Central	Kabwe	Davon Health Shop	Yes	No	Partial
111	Central	Kabwe	KabweCentral Hospital	No	N/A	N/A
112	Central	Kabwe	Mahatma Ghandi Memorial Clinic	No	N/A	N/A
113	Central	Kabwe	KabwePharmacy	Yes	Yes	Partial

	Province	District	Health Facility	ZAMRA Registration	Post Licensing Inspection By ZAMRA	AdheranceTo Recommendaations
114	Central	KapiriMposhi	Chawama Health Centre	No	N/A	N/A
115	Western	Mongu	Seraphim Health Shop	Yes	Yes	Partial
116	Western	Mongu	MonguRegional Hub (Wholesale)	No	N/A	N/A
117	Western	Mongu	Smart Pharmacy Limited	Yes	Yes	Partial
118	Western	Mongu	P &G Health Care	Yes	Yes	Partial
119	Western	Mongu	Premium Care Pharmacy	Yes	Yes	Partial
120	Western	Mongu	Freshview Pharmacy	Yes	Yes	Partial
121	Western	Mongu	Mongu District Hospital	No	N/A	N/A
122	Western	Mongu	Lewanika General Hospital	No	N/A	N/A
123	Western	Mongu	Prisons Clinic	No	N/A	N/A
124	Western	Senanga	Senanga General Hospital	No	N/A	N/A
125	Western	Senanga	Senanga Urban Clinic	No	N/A	N/A
126	Western	Senanga	Mbuyoti Pharmacy	Yes	Yes	Partial
127	Western	Senanga	Ultimate Health Shop	Yes	Yes	Partial
128	Western	Kaoma	Luena Camp Hospital	No	N/A	N/A
129	Western	Kaoma	Lesa YeupaBumi Pharmacy	Yes	Yes	Partial
130	Western	Kaoma	Kaoma Pharmacy Limited	Yes	Yes	Partial
131	Western	Kaoma	Kaoma District Hospital	No	N/A	N/A
132	Western	Kaoma	Mulamba Urban Clinic	No	N/A	N/A
133	Western	Kaoma	Joyful Living Pharmacy Limited	Yes	Yes	Partial
134	Western	Kaoma	Mamu Pharmacy	Yes	No	N/A
135	Southern	Livingstone	Livingstone Teaching Hospital.	No	N/A	N/A
136	Southern	Mazabuka	Mazabuka General Hospital	Yes	Yes	Fully
137	Southern	Kazungula	Kazungula District Hospital	No	N/A	N/A
138	Southern	Kazungula	Medicine World Pharmacy	Yes	Yes	Partial
139	Southern	Kazungula	Bekuchi Pharmacy	Yes	Yes	Partial
140	Southern	Kazungula	Nico Memorial Clinic	Yes	No	N/A
141	Southern	Livingstone	Noor Pharmaceuticals	Yes	Yes	Partial
142	Southern	Chirundu	Kandende Pharmacy And Cosmetic Limited	Yes	Yes	Partial
143	Southern	Chirundu	Sebry Clinic	No	No	N/A
144	Southern	Chirundu	Mtendere Mission Hospital	No	Yes	Fully

	Province	District	Health Facility	ZAMRA Registration	Post Licensing Inspection By ZAMRA	AdheranceTo Recommendaations
145	Southern	Chirundu	Chirundu Pharmacy	Yes	Yes	Fully
146	Southern	Chirundu	Skyline Best Health Care - Health Shop	Yes	Yes	Partial
147	Southern	Livingstone	Livingstone Pharmacy	Yes	Yes	Partial
148	Southern	Livingstone	Safeway Health Shop	Yes	No	N/A
149	Eastern	Chipata	Chipata Chemist	Yes	Yes	Partial
150	Eastern	Chipata	Walela Health Post	No	N/A	N/A
151	Eastern	Chipata	Altaf Memorial Hospital	No	Yes	N/A
152	Eastern	Chipata	Gondar Health Shop	Yes	Yes	Partial
153	Eastern	Katete	St. Francis Hospital	No	N/A	N/A

Appendix 15: Target Vs Product Sampled 2019 to May 2022

No.	Year	Human related products	Targeted number	Actual number
			sampled	sampled
		Reproductive Health	8	1
		Essential Medicines	28	4
		Antiretroviral	5	2
		Anti – TBs	8	3
1	2019	Non Communicable Diseases	3	1
		Urgent Health Public Concerns	10	1
		Potential Substandard/Spurious/Falsely-labelled/Falsified/ Counterfeit Medical Products (SSFFCs)	14	1
Total Sampled			76	13
Percentage sampled				17.1%
		Reproductive Health	7	4
		Essential Medicines	39	30
(		Antiretroviral	9	9
7	7070	Anti – TBs	8	3
		Non-Communicable	5	4
		APIs from Local manufacturers	11	8
Total Sampled			92	55
Percentage sampled				72.3%

No.	Year	Human related products	Targeted number sampled	Actual number sampled
		Reproductive Health	12	7
		Essential Medicines	39	30
,	1000	Antiretroviral	6	6
n	2021	Anti – TBs	6	5
		Non Communicable	5	3
		APIs	11	9
Total Sampled			85	09
Percentage sampled				70.6
4	May 2022	Reproductive Health	80	0
		Essential Medicines	55	12
		Antiretroviral	13	6
		Anti – TBs	11	04
		Non Communicable	10	01
		In – Vitro Diagnostics	60	00
		Allied substances	90	03
		APIs	11	03
Total Sampled			123	32
Percentage sampled				26.0%

Appendix 16: List of Medicines Recalled 2019 -2022

			2019		
ON	Name of Product	Manufacturer	Batch No.	Reasons(s) for Recall	Date of Recall
	Ringers Lactate	IDC Limited, Zambia	2802180	Foreign particulate matter	19-02-2019
2	Gentamed Injection	CSPS Ouyi, China	180107 & 180108	Adverse Drug Reactions	27-03-2019
3	Co-Amoxyclav Suspension	Sandoz (SA), South Africa	HT 6196,6199,6201 & 7922	Poor container closure system	03-06-2019
4	Atazor -R Tablets	Emcure, India	EM 83043,83044,83045,83047,83049, 83051, 83062, 83064	Out of trend impurity (after 02/2020)	26-08-2019
5	Isoniazid 100mg Tablets	NRB, Zambia	1019001	Assay test	02-09-2019
9	Ciprofloxacin 250 mg tablets	BMPCL, Zambia	80917	Weight variation	03-09-2019
7	Dazole Cream	Dawa, Kenya	Several	Leakage of contents due to poor packaging	27-09-2019
∞	Ranitidine	Several	All (Withdraw)	Contamination with NDMA	02-10-2019
6	Metronidazole IVF	Denis Chem Lab(Hetero), India	1905047014 and 1905047011	Discoloration	31-10-2019
10	Diclofenac Injection	CSPC Ouyi, China	170841	Discoloration	22-11-2019
11	Camoxy Capsules	Cameo Healthcare Pvt Limited, India	CP007	Assay test	13-12-2019
			0,000		
1	Amlodipine 5mg Tablets	Wintech Pharmaceuticals, India	ET-909, ET -907	Non-compliant Organoleptic + Friability	20-01-2020
2	Cloxacillin 250 mg Capsules	Cameo Healthcare Pvt Limited. India	CP 003	Appearance(Foreign matter on capsules)	21-01-2020

No.	Name of Product	Manufacturer	Batch No.	Reasons(s) for Recall	Date of Recall
3	Aspirin 75mg Tablets	Wintech Pharmaceuticals, India	ET-891, ET-905, ET-906	Non-compliant with Assay+ Organoleptic tests	23-01-2020 & 07-12-2020
4	Pediatric Cotrimoxazole Oral Suspension.	Lincoln Pharmaceuticals, India	CT8005 -CT 8099 - CT 8100 - CT 8158 - CT 9001- CT 9071	Discoloration due to out of trend impurity	03-04-2020& 24-07-2020
5	Dexamycin Eye/Ear Drops	Vigor Laboratories, India	DY-1803	Faulty container closure sys. Product leakages	19-05-2019
9	Trolox Suspension	Osaka Pharmaceuticals, India	D1928	Caking	27-05-2020
7	Panadol Tablets	Pharmanova (Z) Limited	550520	Tablet embedded with foreign material	03-07-2020
∞	Paracetamol 500 mg Tablets	Prashi Pharma Limited, India	PPYP01-16	Non-compliant Assay Organoleptic + Friability	09-09-5050
6	Paracetamol 100 mg Tablets	Prashi Pharma Limited, India	PPYP02	Non-compliant with Assay & Friability Tests	17-09-2020
			2021		
-	Luxcee (Vitamin C) Tablets	Kausikh Therapeutics Limited, India	KE20204	Product discoloration	17-02-2021
7	Aspirin Tablets USP 75 mg	Wintech Pharm., Bhor Int'l, India.	ET-891; ET-905	Non-compliant to Assay, non-compliant appearance+oranoleptic	25-01-2021
3	Pharmadol Syrup	Yash Life Sciences Limited	060919,070919,080919,090919 and 100919	crystallisation	08-01-2021
4	Bupivacaine Hychloride inj. USP 0.5% w/v	Bharat ParenteralsLimited., India	P0572	Wrong labelling for the route of administration	04-03-2021

bawa Limited, Kenya and 2002191 to packaging & storage requirements  B Bharat ParenteralsLimited. T0094, T0097 AND T0098 papearance and Equirements  Shalina Laboratories, India ALL perection of Africa Africa Denk Pharma Germany  Hetero Labs Limited, India LOA200321C & LOA20307B Containing foreign material india LoA20091 Containing foreign material india Pfizer, Inc and BioNTech FL3204 Failed Assay Test  Sambia Life Sciences Limited, and BioNTech Flatch and BioNTech Flatch and BioNTech Flatch and BioNTech Flatch Sambia  Davi Davis Denk Pharma over the service of the serv	Nam	Name of Product	Manufacturer	Batch No.	Reasons(s) for Recall	Date of Recall
Bharat ParenteralsLimited, India Shaina Laboratories, India ALL Siene Pharma Cutical Africare Pharma Cutical India Betro Labs Limited, India Some Delta Containing foreign material India Some BioNTech India Stant Healthcare Limited, India Stant Healthcare	Dazole Cream (Clotrimazole 1% w/w)	imazole	Dawa Limited, Kenya	1911035, 1911036,1911037, 2002189 and 2002191	non-compliant with respect to packaging & storage requirements	13-04-2021
Shalina Laboratories, India ALL ALL ALL Arica  Denk Pharma Dynamics, South Africar  Africar  Denk Pharma Germany ALL  Africure Pharmaceuticals, India Hetero Labs Limited, India Benk Pharma GmbH. S Kant Healthcare Limited, India S Kant Healthcare Limited, India Benk Pharma GmbH. S Kant Healthcare Limited, India Africare Containing foreign material India S Kant Healthcare Limited, India S Kant Healthcare Limited, Appearance Containing a visible particle Yash Life Sciences Limited, Aurican  ADL  A-chloazidomethyltetetrazole Impurity A-chloazidomethyltetetrazole India  Bark Discoloration leading to Containing foreign material Agnoration Ayash Life Sciences Limited, Arabbia	Folic Acid Tablets BP 5MG	P 5MG	Bharat ParenteralsLimited., India	T0094, T0097 AND T0098	Non-compliant with respect to appearance	12-03-2021
Pharma Dynamics, South AfricaALL ALLDetection of 4-chloazidomethyltetetrazole impurityDenk Pharma, Germany IndiaALL Africure Pharmaceuticals, IndiaALL 4-chloazidomethyltetetrazole impurityAfricure Pharmaceuticals, India2102 AppearanceAppearance AppearanceIndiaLOA200321C & LOA20307BOOT Azido impurityDenk Pharma GmbH. 	Cevite (Vitamin C) 500mg tablets	500mg	Shalina Laboratories, India	Various	Discoloration and melting of some batches	10-02-2021
Denk Pharma, Germany IndiaALL 4-chloazidomethyltetetrazole impurityDetection of 4-chloazidomethyltetetrazole impurityAfricure Pharmaceuticals, India2102AppearanceAfricure Pharmaceuticals, IndiaLOA200321C & LOA20307BOOT Azido impurityDenk Pharma GmbH. KG,Germany3940Dark Discoloration leading to considerable impuritiesS Kant Healthcare Limited, IndiaPB20091Containing foreign material19Pfizer, Inc and BioNTechFL3204Containing a visible particleYash Life Sciences Limited, Zambia390322Failed Assay Test	Zartan Co. 50/12.5 & 100/12.5 Tablets	સ્ત્ર	Pharma Dynamics, South Africa	ALL	Detection of 4-chloazidomethyltetetrazole impurity	28-09-2021
hindia Hetero Labs Limited, India LOA200321C & LOA20307B OOT Azido impurity Denk Pharma GmbH. 3940 Containing foreign material India India Pfizer, Inc and BioNTech Sash Life Sciences Limited, 390322 Failed Assay Test  Appearance  Appearance Appearance Appearance OOT Azido impurity Containing to impurities Containing a visible particle Failed Assay Test Failed Assay Test	Losar-Denk&Colosar- DenkProdcts		Denk Pharma, Germany	ALL	Detection of 4-chloazidomethyltetetrazole impurity	05-10-2021
Hetero Labs Limited, India LOA200321C & LOA20307B OOT Azido impurity  Denk Pharma GmbH. 3940 Dark Discoloration leading to considerable impurities  S Kant Healthcare Limited, PB20091 Containing foreign material lindia  Pfizer, Inc and BioNTech FL3204 Containing a visible particle  Yash Life Sciences Limited, 390322 Failed Assay Test	Metrosim Tablets 200 mg	0 mg	Africure Pharmaceuticals, India	2102	Appearance	26-08-2021
Hetero Labs Limited, IndiaLOA200321C & LOA20307BOOT Azido impurityDenk Pharma GmbH. KG,Germany3940Dark Discoloration leading to considerable impuritiesS Kant Healthcare Limited, IndiaPB20091Containing foreign materialPfizer, Inc and BioNTechFL3204Containing a visible particleYash Life Sciences Limited, Zambia390322Failed Assay Test				2022		
Denk Pharma GmbH.  KG, Germany S Kant Healthcare Limited, India India  Pfizer, Inc and BioNTech Yash Life Sciences Limited, Zambia  Dark Discoloration leading to considerable impurities  Containing foreign material  Containing a visible particle Failed Assay Test  Failed Assay Test	Losagen Tablets 50 & 100mg	k 100mg	Hetero Labs Limited, India	LOA200321C & LOA20307B	OOT Azido impurity	07-02-2022
S Kant Healthcare Limited, PB20091 Containing foreign material India  19 Pfizer, Inc and BioNTech FL3204 Containing a visible particle  Yash Life Sciences Limited, 390322 Failed Assay Test	Panto-Denk 40 Gatro-resistant tablets	0	Denk Pharma GmbH. KG,Germany	3940	Dark Discoloration leading to considerable impurities	11-03-2022
Pfizer, Inc and BioNTech FL3204 Containing a visible particle  Yash Life Sciences Limited, 390322 Failed Assay Test	Cotrikant (Paed. Cotrimoxazole) 240mg/5ml	mg/5ml	S Kant Healthcare Limited, India	PB20091	Containing foreign material	27-04-2022
Yash Life Sciences Limited, 390322 Failed Assay Test	Pfizer-BioNTech COVID-19 Vaccine	OVID-19	Pfizer, Inc and BioNTech	FL3204	Containing a visible particle	29-04-2022
	Ciplrofloxacin Tablets BP 250mg	ets BP	Yash Life Sciences Limited, Zambia	390322	Failed Assay Test	12-05-2022

Appendix 17: Qualification and Maintenance of Laboratory Equipment 2019 to 2022

## 2019

No.	Equipment ID	Maintenance Activity Performed	Service Done by	Due Date (x)	Date Done (y)	Lead Time (y-x) Days	Lead Time (y-x) Status as at October 2022 Days
	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC1)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1		ı	ı	Unavailability of service providers as a result of the COVID 19 movement restrictions
	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC 2)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	1	1	ı	Unavailability of service providers as a result of the COVID 19 movement restrictions
	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC 3)	<ul> <li>Servicing and maintenance</li> <li>Qualification and Calibration</li> <li>Performance Verification</li> </ul>	1	ı	ı	ı	Unavailability of service providers as a result of the COVID 19 movement restrictions
	High Pressure Liquid Chromatography PerkinElmer ALTUS (HPLC4)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	1	ı	ı	Unavailability of service providers as a result of the COVID 19 movement restrictions
	PerkinElmer Lambda 35 UV/ VIS Spectrophotometer (UV- Vis 1)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	1			Unavailability of service providers as a result of the COVID 19 movement restrictions
	PerkinElmer Spectrum 100 FTIR Spectrophotometer (FTIR 1)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	1			Unavailability of service providers as a result of the COVID 19 movement restrictions

No.	Equipment ID	Maintenance Activity Performed	Service Done by	Due Date (x)	Date Done (y)	Lead Time (y-x) Days	Status as at October 2022
	Weighing Balance (Semi- Micro Balance 3)	Calibration	Zambia Metrology Agency	17/06/2019	12/07/2019	25 Days	<ul> <li>The calibration was done; however, the service provider did not show up on time as they had strict schedule to follow</li> <li>Servicing and maintenance are done internally according to the approved schedule on the Z/LS/ L201</li> </ul>
	E2 Weight Set	Calibration	Zambia Metrology Agency	25/12/2019	28/01/2020	34 Days	Calibration was done
	Disintegration Tester 1	Calibration	Zambia Metrology Agency	12/11/2018	09/01/2019	58 Days	<ul> <li>The calibration was done; however, the service provider did not show up on time as they had strict schedule to follow</li> <li>Servicing and maintenance are done internally according to the approved schedule on the Z/LS/ L201</li> </ul>
	Dissolution Tester 1	Calibration	Zambia Metrology Agency	12/11/2018	09/01/2019	58 Days	<ul> <li>The calibration was done; however, the service provider did not show up on time as they had strict schedule to follow</li> <li>Servicing and maintenance are done internally according to the approved schedule on the Z/LS/ L201</li> </ul>

## 2020

No.	Equipment ID	Maintenance Activity Performed	Service Done by	Due Date (x)	Date Done (y)	Lead Time (y-x) Days	Comment
	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC1)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	1	1	ı	Unavailability of service providers as a result of the COVID 19 movement restrictions
	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC 2)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	1	1		Unavailability of service providers as a result of the COVID 19 movement restrictions
	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC 3)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	1	1		Unavailability of service providers as a result of the COVID 19 movement restrictions
	High Pressure Liquid Chromatography PerkinElmer ALTUS (HPLC4	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	1	1		Unavailability of service providers as a result of the COVID 19 movement restrictions
	Thermo Scientific HPLC 5 (Newly Installed)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	Anatec Analytical Technology	1	01/02/2020		Instrument was installed in February, 2020. Installation qualification and operation qualification were done
	Thermo Scientific HPLC 6 (Newly Installed)	<ul> <li>Servicing and maintenance</li> <li>Qualification and Calibration</li> <li>Performance Verification</li> </ul>	Anatec Analytical Technology		01/02/2020		Instrument was installed in February, 2020. Installation qualification and operation qualification were done

Equipment ID		Maintenance Activity Performed	Service Done by	Due Date (x)	Date Done (y)	Lead Time (y-x) Days	Comment
PerkinElmer Lambda 35 UV/VIS Spectrophotometer (UV- Vis 1)	Se Ou	<ul> <li>Servicing and maintenance</li> <li>Qualification and Calibration</li> <li>Performance Verification</li> </ul>		1	ı	1	Unavailability of service providers as a result of the COVID 19 movement restrictions
PerkinElmer Spectrum 100 • Ser FTIR Spectrophotometer • Per (FTIR 1)		<ul> <li>Servicing and maintenance</li> <li>Qualification and Calibration</li> <li>Performance Verification</li> </ul>	ı	ı	ı	ı	Unavailability of service providers as a result of the COVID 19 movement restrictions
Weighing Balance (Semi-Micro Balance 3)		Calibration	Zambia Metrology Agency	11/07/2020	06/08/2020	26 Days	<ul> <li>The calibration was done; however, the service provider did not show up on time as they had strict schedule to follow</li> <li>Servicing and maintenance are done internally according to the approved schedule on the Z/LS/L201</li> </ul>
Weighing Balance (Metttler Toledo Semi -Micro Balance 4)		Calibration	Zambia Metrology Agency	1	06/08/2020	ı	<ul> <li>New installation</li> <li>Installation qualification</li> <li>(IQ) and operation</li> <li>qualification (OQ) were</li> <li>done</li> </ul>
Weighing Balance (Metttler Toledo Micro Balance 5)		Calibration	Zambia Metrology Agency	1	06/08/2020		<ul> <li>New installation</li> <li>Installation qualification (IQ) and operation qualification (OQ) were done</li> </ul>

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No.	Equipment ID	Maintenance Activity Performed	Service Done by	Due Date (x)	Date Done (y)	Lead Time (y-x) Days	Comment
	E2 Weight Set	Calibration	Zambia Metrology Agency	25/12/2019	28/01/2020	34 Days	Calibration done
	Disintegration Tester 1	Calibration	Zambia Metrology Agency	08/01/2020	16/09/2020	46 Days	Calibration was done
	Dissolution Tester	Calibration	Zambia Metrology Agency	08/01/2020	16/09/2020	46 Days	Calibration was done

## 2021

No.	Equipment ID	Maintenance Activity Performed	Service Done by	Due Date (x)	Date Done (y)	Lead Time (y-x) Days	Comment
	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC1)	• Servicing and maintenance • Qualification and Calibration • Performance Verification Service	Alliance Analytical Service	01/07/2020	21/05/2021	324 Days	The delay was attributed to unavailability of service providers owing to the COVID 19 movement restrictions
	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC 2)	<ul> <li>Servicing and maintenance</li> <li>Qualification and Calibration</li> <li>Performance Verification</li> </ul>	Alliance Analytical Service	01/07/2020	20/05/2021	323 Days	The delay was attributed to unavailability of service providers owing to the COVID 19 movement restrictions

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38

Comment	The delay was attributed to unavailability of service providers owing to the COVID 19 movement restrictions	The delay was attributed to unavailability of service providers owing to the COVID 19 movement restrictions	The delay was attributed to unavailability of service providers owing to the COVID 19 movement restrictions	There were no service providers available due to the COVID 19 movement restrictions	There were no service providers available due to the COVID 19 movement restrictions COVID 19 movement restrictions	The delay was attributed to unavailability of service providers owing to the COVID 19 movement restrictions
Lead Time (y-x) Days	324 Days	324 Days	324 Days	ı	ı	323 Days
Date Done (y)	20/05/2021	21/05/2021	21/05/2021	ı	,	20/05/2021
Due Date (x)	01/07/2020	01/07/2020	01/07/2020	01/02/2020	01/02/2020	01/07/2020
Service Done by	Alliance Analytical Service	Alliance Analytical Service	Alliance Analytical Service	ı	ı	Alliance Analytical Service
Maintenance Activity Performed	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	<ul> <li>Servicing and maintenance</li> <li>Qualification and Calibration</li> <li>Performance Verification</li> </ul>	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>
Equipment ID	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC 3)	High Pressure Liquid Chromatography PerkinElmer ALTUS (HPLC4	PerkinElmer Lambda 35 UV/VIS Spectrophotometer (UV-Vis 1)	THERMO SCIENTIFIC HPLC 5	THERMO SCIENTIFIC HPLC 6	PerkinElmer Spectrum 100 FTIR Spectrophotometer (FTIR 1)
O N						

No.	Equipment ID	Maintenance Activity Performed	Service Done by	Due Date (x)	Date Done (y)	Lead Time (y-x) Days	Comment
	Weighing Balance (Semi- Micro Balance 3)	Calibration	Zambia Metrology Agency	05/08/2021	02/09/2021	28 Days	Calibration was done
	Weighing Balance (Metttler Toledo Semi -Micro Balance 4)	Calibration	Zambia Metrology Agency	05/08/2021	02/09/2021	28 Days	Calibration was done
	Weighing Balance (Metttler Toledo Micro Balance 5)	Calibration	Zambia Metrology Agency	05/08/2021	02/09/2021	28 Days	Calibration was done
	E2 Weight Set	Calibration	Zambia Metrology Agency	27/01/2021	27/01/2021	0 Days	Calibration was done
	Disintegration Tester 1	Calibration	Zambia Metrology Agency	15/09/2021	20/10/2021	35 Days	Calibration was done
	Dissolution Tester	Calibration	Zambia Metrology Agency	15/09/2021	20/10/2021	35 Days	Calibration was done

## October 2022

No.	Equipment ID	Maintenance Activity Performed	Service Done by	Due Date (x)	Date Done (y)	Lead Time (y-x) Days	Comment
	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC1)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	21/05/2021	ı	ı	Payment for the service has been approved; awaiting service providers
	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC 2)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	20/05/2021	1	1	Payment for the service has been approved; awaiting service providers
	High Pressure Liquid Chromatography PerkinElmer FLEXAR (HPLC 3)	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	20/05/2021	1	1	Payment for the service has been approved; awaiting service providers
	High Pressure Liquid Chromatography PerkinElmer ALTUS (HPLC4	<ul><li>Servicing and maintenance</li><li>Qualification and Calibration</li><li>Performance Verification</li></ul>	1	21/05/2021	1	1	Payment for the service has been approved; awaiting service providers
	THERMO SCIENTIFIC HPLC 5	<ul> <li>Servicing and maintenance</li> <li>Qualification and Calibration</li> <li>Performance Verification</li> </ul>	Anatec Analytica Technology	02/02/2021	23/03/2022	1	Instrument annualservicing andmaintenance still valid, but recently developed a fault; the tungsten lampgot burnt- Payment for the faulty component has already been made, awaiting its courier

THERMO SCIENTIFIC Outsification and calibration Analytica Ferkine Emer (Outsification and Calibration Spectrophotometer (Semi-Micro Balance 4)  Weighing Balance (Weighing Balance 4)  Weighing Balance (Weighing Balance 4)  Weighing Balance (Calibration Calibration Calibratic Calibration Calibration Calibration Calibration Calibratic Calibration Calibratic	Equipment ID	Maintenance Activity Performed	Service Done by	Due Date (x)	Date Done (y)	Lead Time (y-x) Days	Comment
• Servicing and maintenance • Qualification and Calibration • Performance Verification • Performance V	NTIFIC	<ul> <li>Servicing and maintenance</li> <li>Qualification and Calibration</li> <li>Performance Verification</li> </ul>	Anatec Analytica Technology	01/02/2021	24/03/2022	1	Instrument annual servicing and maintenance still valid
• Servicing and maintenance • Qualification and Calibration • Performance Verification • Performance Verification  Calibration  Calibration  Calibration  Zambia  Calibration  Metrology  Calibration  Zambia  Calibration  Metrology  Calibration  Zambia  Calibration  Metrology  Calibration  Calibr	VIS	<ul> <li>Servicing and maintenance</li> <li>Qualification and Calibration</li> <li>Performance Verification</li> </ul>	ı	21/05/2021	•	•	<ul> <li>Awaiting expert to carry out annual maintenance service.</li> <li>Equipment qualification and calibration is done internally with valid and traceable reference standards</li> </ul>
Calibration         Zambia Agency         02/09/2022         09/09/2022           Agency         Zambia Agency         02/09/2022         09/09/2022           Agency         Agency         Agency         09/09/2022           Agency         Agency         09/09/2022           Agency         Agency         09/09/2022	TIR	<ul> <li>Servicing and maintenance</li> <li>Qualification and Calibration</li> <li>Performance Verification</li> </ul>	ı	21/05/2021	1	ı	<ul> <li>Awaiting expert to carry out annual maintenance service.</li> <li>Equipment qualification and calibration is done internally with valid and traceable reference standards</li> </ul>
Calibration         Zambia Metrology         02/09/2022         09/09/2022           Agency         Zambia Metrology         02/09/2022         09/09/2022	se Jance 3)	Calibration	Zambia Metrology Agency	02/09/2022	09/09/2022	7 Days	Instrument annual servicing and maintenance still valid
Zambia         Metrology         02/09/2022         09/09/2022	ce Semi 4)	Calibration	Zambia Metrology Agency	02/09/2022	09/09/2022	7 Days	Calibration within its validity
Agency	nce o Micro	Calibration	Zambia Metrology Agency	02/09/2022	09/09/2022	7 Days	Calibration within its validity

No.	Equipment ID	Maintenance Activity Performed	Service Done by	Due Date (x)	Date Done (y)	Lead Time (y-x) Days	Comment
	E2 Weight Set	Calibration	Zambia Metrology Agency	26/01/2022	01/02/2022	6 Days	<ul><li>Calibration done</li><li>Instrument calibration still valid</li></ul>
	Disintegration Tester 1	Calibration	Zambia Metrology Agency	19/10/2022	03/11/2022	15 Days	Instrument annual servicing and maintenance still valid
	Dissolution Tester 1	Calibration	Zambia Metrology Agency	19/10/2022	03/11/2022	15 Days	Instrument annual servicing and maintenance still valid

Appendix 18: Planned vs Actual Sensitisation

	Percentage target achievement	46.15	0	0	100	25		
	Actual acl	9			0009		9	2
					)9		_	
Sep-22	Planned	13	4	10	0009	4	8	4
	Percentage target achievement	100	100	09	100	100	25	50
	Actual	13	4	9	0009	4	2	2
2021	Planned	13	4	10	0009	4	8	4
	Percentage target achievement	76.92	150	06	100	50	50	50
	Actual	10	9	6	0009	2	4	2
2020	Planned	13	4	10	0009	4	8	4
	Percentage target achievement	53.85	No Target but had 4 TV adverts	No Target but had 4 TV and 2 Radio adverts	100	50	114.29	100
	Actual	7	4	9	4000	2	8	4
2019	Planned	13	0	0	4000	4	7	4
Activity		Number of Sensitisation programmes on both print and electronic media	TV/Radio adverts	Number of Notices & Adverts published	Number of Information, Education and Communication (IEC) materials	Sensitisation campaigns in selected communities using drama performances	Participation at Public National Events	Stakeholder Engagement
N/S		-	7	က	4	v	9	1

Appendix 19: Sensitisation Activities Undertaken 2019- September 2022

YEAR	MEDIUM	OBJECTIVE	COVERAGE
2019	Radio Christian voice	Create awareness of: - the general mandate of ZAMRA - dangers of self-prescribed medicines, - Report adverse medicines reactions and labelling requirements.	<ul> <li>Lusaka,</li> <li>Chipata,</li> <li>Ndola,</li> <li>Kitwe, Kapiri,</li> <li>Livingstone,</li> <li>Kasama</li> <li>Solwezi</li> </ul>
	Community Sensitisation using drama performances	- Create awareness against drug abuse and illegal sale of medicines.	Lusaka's Chipata and Garden compounds
	Develop and Print IEC and Corporate Promotional Material. (Developed for distribution and use during national events and exhibitions).	Create awareness of: The general mandate of ZAMRA Importance of reporting adverse medicines reactions and labelling requirements.	Not provided
	Participate in Local and International Exhibitions e.g. The 55th Zambia International Trade Fair (ZITF) Exhibition in Ndola and the 93rd Zambia Agricultural and Commercial Show, Lusaka.	Create awareness of:  - The general mandate of ZAMRA - Dangers of self-prescribed medicines, - Report adverse medicines reactions and labelling requirements.	Lusaka and Ndola
	Stakeholder Engagement	consulting various stakeholders on the development of ZAMRA's five years business and two years strategic plans-Bridges Limited, a consultancy firm developed these two plans presided over the sessions and received submissions from various stakeholders which included  Pharmacy Industry, Cooperating Partners, Government Agencies, Civil Society Organisations, the media and the general public	From 12th to 13th September 2019 at Best Western Plus Hotel in Lusaka

COVERAGE	- Countrywide - Countrywide - Lusaka - Countrywide	- Major towns	-Lusaka - Ndola - Chipata, -Livingstone - Solwezi - Kasama	-Lusaka - Ndola - Chipata, -Livingstone - Solwezi - Kasama
OBJECTIVE	<ul> <li>To sensitise the public on the following:</li> <li>Mandate of the Authority;</li> <li>PMS Activities;</li> <li>Pharmacovigilance and Medicines Safety monitoring; and</li> <li>Misuse of Medicines.</li> </ul>	<ul> <li>Registers</li> <li>Notice on registration of disinfectants, antiseptics and allied substances</li> <li>Notice on Rufedol</li> <li>Notice on change of premises</li> <li>Notice on payment for Annual returns or no change return</li> <li>Notice/advert on COVID 19</li> <li>Three unapproved adverts were produced on the Authorities mandate</li> </ul>	<ul> <li>Enhancing visibility and collaborations with stakeholders as well as to raise public awareness on the Authorities mandate</li> </ul>	<ul> <li>Facilitate visibility of the Authority at offices and public events</li> </ul>
MEDIUM	Radio and TV - ZNBC - Diamond TV - Millennium Radio - ZANIS	Placement of adverts in newspapers/magazines/directories Times of Zambia Zambia daily Mail Daily Nation Newspaper	Participation of Public National Events and exhibitions - International Women's Days and Consumer rights day	Develop and print IEC, corporate and promotion materials were developed and printed for use at regional and sub offices at ZAMRA  - Four pop ups - Four ZAMRA flags - Telescopic (4) - Tear drops (4)
YEAR	2020			

COVERAGE	- Lusaka	- Lusaka	Countrywide	Major towns	Lusaka
OBJECTIVE	<ul> <li>To foster collaboration and engagement with stakeholders as well as increase visibility thereby building the image of the Authority.</li> </ul>	To mitigate the effects of COVID 19, ZAMRA donated a consignment of alcohol based hand sanitizer valued at K50,000 to MoH	Raising public awareness on the Authority's mandate key massage included:  - Illegal drug stores;  - Marketing Authorization;  - COVID-19 Vaccines;  - Hand sanitisers and disinfectants;  - Product recalls; and  - Misuse of Medicines.	<ul> <li>Notices and circulars that were published</li> <li>Notice on importation of allied substances (IVD's);</li> <li>Recall notice on Lostan containing products;</li> <li>Notice on payment of Annual Returns or No Change Return;</li> <li>Notice/advert on COVID-19;</li> <li>Independence Day celebration message and Presidential Congratulatory message</li> </ul>	- Donation of assorted items, COVID-19 related mitigation products such as hand sanitisers and disinfectants.
MEDIUM	Development and Implementation of a Communication Strategy/Stakeholder Engagement Plan - HPCZ - CHAZ - MoH	Corporate Social Responsibility	Radio and television	Placement of Adverts in Newspapers /Magazines/ Directories - Times of Zambia - Zambia Daily Mail - Daily Nation Newspapers.	Public National Events & Exhibitions - commemorated International Women's Day and Consumer Rights Day (House of Moses)
YEAR			2021		

COVERAGE	S	Not provided	- Solwezi, - Chipata	- Kasama	- Lusaka
OBJECTIVE	To enhance public awareness and sensitisation on the Authority's mandate;	<ul> <li>Brochures, fliers and folders</li> <li>T-shirts, shirts, face masks and caps</li> <li>Branded Gazebo</li> </ul>	Community sensitisation in collaboration with regional offices to sensitise communities on rational use of medicines and the Authority's mandate through	<ul> <li>Sensitisation using the ZANIS public address system.</li> <li>Radio programmes</li> </ul>	To sensitise the media on a number of issues bordering on the Authority's mandate as the media remains a key stakeholder in sensitising and educating the masses on regulatory information, as well as influencing positive altitudes and change towards rational use of medicines.
MEDIUM	Lance shows the second	Development and printing of LEC, corporate and promotional materials	Conduct community sensitisation on the Authority's mandate		Media Engagement Meeting
YEAR					

