REPUBLIC OF ZAMBIA

REPORT

OF THE

COMMITTEE ON HEALTH, COMMUNITY DEVELOPMENT AND SOCIAL SERVICES

ON THE

PERFORMANCE AUDIT REPORT OF THE AUDITOR GENERAL ON THE CONTROL AND REGULATION OF MEDICINES IN ZAMBIA 2019 - 2022

FOR THE

THIRD SESSION OF THE THIRTEENTH NATIONAL ASSEMBLY

Published by the National Assembly of Zambia

FOREWORD

Hon Madam Speaker, pursuant to Standing Order 198(g), of the National Assembly of Zambia Standing Orders, 2021, the Committee on Health, Community Development and Social Services is vested with the power to consider audit reports. Thus, the Committee was mandated to consider the Performance Audit Report of the Auditor General on the Control and Regulation of Medicines in Zambia, 2019 – 2022.

In order to scrutinise the Performance Audit Report, the Committee held nine meetings and sought both written and oral submissions from stakeholders. The stakeholders, who appeared before the Committee, are listed at Appendix II.

The Committee is grateful to all stakeholders who tendered both written and oral submissions. The Committee further wishes to thank you, Madam Speaker, for affording it an opportunity to carry out its work. It also appreciates the services rendered by the Office of the Clerk of the National Assembly and his staff throughout the Committee's deliberations.

Dr Christopher K Kalila, MP
CHAIRPERSON

December, 2023
LUSAKA

Table of Contents

List of Acronyms

MoH	Ministry of Health
ZAMRA	Zambia Medicines and Regulatory Authority
MAs	Marketing Authorisations
GMP	Good Manufacturing Practices
CTD	Common Technical Document
HPCZ	Health Professions Council of Zambia

1.0 Membership of the Committee

The Committee consisted of: Dr Christopher K Kalila, MP (Chairperson); Mrs Marjorie Nakaponda, MP (Vice Chairperson); Mr Masautso Tembo, MP; Mr Miles Sampa, MP; Mr Joseph S Munsanje, MP; Mr Leevan Chibombwe, MP; Mr Monty Chinkuli, MP; Mr Paul Chala, MP; Mr Heartson Mabeta, MP; and Mr Alex Katakwe, MP.

2.0 Auditor General's Comments

The Auditor General informed the Committee that in accordance with the Provisions of Article 250 of the *Constitution of Zambia*, *Public Audit Act, No. 13 of 1994* and *the Public Finance Management Act, No. 1 of 2018*, the Office of the Auditor General was mandated to carry out performance audits in ministries, provinces, Government departments and agencies (MPAs) and to report the results to the Republican President and to the National Assembly.

2.1 Background to the Audit

The Auditor General informed that Committee that performance auditing was an independent, objective and reliable examination of whether Government undertakings, systems, operations, programmes, activities or organisations were operating in accordance with the principles of economy, efficiency and effectiveness and whether there was room for improvement. This type of audit sought to promote economical, effective and efficient governance as well as contribute to accountability, transparency and quality delivery of public services.

2.2 Motivation of the Audit

The Auditor General submitted that since medicines were essential to health care and that they should be available to all citizens, it was, therefore, important to ensure that medicines were safely used every day to treat diseases. However, there had been adverse events over the years to prove that consumption of medicines also carried risks. It was, therefore, a fundamental role of the Government to protect and promote the health and safety of the public through a well-functioning health-care system that ensured available and affordable medical products that were safe, effective and of assured quality.

The Committee was informed that the audit was motivated by a number of factors namely:

i) inadequate regulation of dangerous drugs in the country, which had led to widespread abuse of dangerous drugs in communities;
ii) anti-malarial drugs which were reported to be of poor quality with results showing that 10.3 per cent of tested drugs contained less than 80 per cent of the labelled active pharmaceutical ingredient;
iii) 22 out of 125 essential medicines sampled from hospitals in three provinces namely: Central, Copperbelt and Lusaka by the Zambia Medicines Regulatory Agency did not pass the Global Pharma Health Fund's Minilab tests in 2019; and

iv) with the advent of the Corona Virus pandemic (COVID-19), there were reports of widespread abuse of antibiotics and the use of other prescription drugs such as Ivermectin.

Hence the audit was carried out to establish the extent of the control and regulation of medicines done by the Zambia Medicines and Regulatory Authority (ZAMRA) through the Ministry of Health.

2.3 Objectives of the Performance Audit Report

The audit objective was to assess whether the measures put in place by ZAMRA were efficient and effective in protecting and enhancing public health through the control and regulation of medicines.

2.4 Audit Scope and Coverage

The audit covered the period 2019 to 2022. The target population was ZAMRA under the MoH. In this regard, six out of the ten provinces, eighteen out of the 116 districts were purposively sampled. From the selected districts, 153 premises compromising: fourteen health shops, fifty-six retail pharmacies, ten wholesale pharmacies, sixty-two public hospital pharmacies, eight registered private hospital pharmacies, and three drug manufacturing companies were randomly sampled. The areas visited were selected districts in Lusaka, Eastern, Southern, Central, Western and Copperbelt Provinces. The purposive sampling was used to select provinces and districts while regulated premises 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.

2.5 Audit Questions

Based on the audit objectives, the audit questions were as follows:

a) to what extent is Zambia Medicines and Regulatory Authority efficient and effective in the control and monitoring of medicines in the country?
b) to what extent has ZAMRA ensured the formation of strategic alliances with key stakeholders?

3.0 CONSIDERATION OF STAKEHOLDER SUBMISSIONS BY THE COMMITTEE

The Committee considered submissions from various stakeholders as per Appendix II. The submissions from the stakeholders and the Permanent Secretary from the MoH as well as the Committee's observations and recommendations are as set out hereunder.

3.1 General Concerns

3.1.1 Funding of ZAMRA

Some stakeholders expressed concern that ZAMRA was not receiving any financial support from the Government. It was further submitted that if ZAMRA was to

effectively discharge its mandate, the Government should consider financial support to the Authority taking into account that failure by ZAMRA to discharge its mandate would put the general public at a serious health risk.

Committee's Observations and Recommendations

In agreeing with the stakeholders, the Committee recommends that the Government should consider funding ZAMRA, so that the grossly understaffed Authority can be able to discharge its mandate effectively.

3.1.2 Delays in Calibrating Laboratory Equipment

Stakeholders expressed concern that laboratory equipment and instruments which were supposed to be kept in optimal working conditions through scheduled performance qualifications and maintenance were not kept as such.

Committee's Observations and Recommendations

The Committee observes with concern that on-time calibration of laboratory equipment which is critical for the smooth running of the laboratory was not being undertaken, as the country has no competent and certified technicians to conduct the required works. In this regard, the Committee recommends that as a way of reducing the down-time of equipment, improved laboratory output and increased customer confidence, ZAMRA should be fully capacitated with certified technicians.

3.2 Specific Audit Concerns

3.2.1 Granting of Marketing Authorisation

Stakeholders were particularly concerned that the number of Marketing Authorisations (MAs) granted during the period under review were low with the analysis showing a downward trend from 512 in 2019 to 214 as of November 2022. Stakeholders were further concerned that ZAMRA had 483 and 1,476 applications which were not evaluated in 2020 and 2021 respectively. In this regard, the stakeholders expressed worry that delayed evaluations coupled with a decrease in granted MAs by ZAMRA, would lead to potential public health risks which may lead to medicine shortages and dumping of unauthorised medicines on the Zambian market.

It was further submitted that, the constrained capacity of ZAMRA, which was accentuated by inadequate staffing and resources was detrimental in overseeing and regulating medicines, particularly impeding the timely processing of MAs for medicines. In this regard, ZAMRA should streamline evaluation processes, utilise technology for faster assessments, and foster communication among staff.

Ministry's Response

The MoH in its submission to the Committee indicated that a first-come first-served approach was being used to evaluate product applications received. It was further submitted that only those applications that met the minimum requirements as

prescribed in the Common Technical Document (CTD) Guidelines qualified to be recommended for grant of marketing authorisation.

To mitigate the noted situation of the low number of MAs issued as of the past audit period (2019 - 2022), ZAMRA had put in place the measures outlined below.

a. Holding Regular Meetings with Applicants

The Committee was informed that ZAMRA had noted over time, that the product dossiers received and subsequently evaluated were of poor quality with regard to compliance to prescribed requirements as per respective Grant of Marketing Authorisation Guidelines - CTD. This led to a low number of product applications meeting the minimum requirements for approval. By holding meetings with applicants, ZAMRA intended to understand the reasons why applicants were failing to compile their product dossiers in the prescribed manner and include the required information thereof. Further, the Committee was informed that ZAMRA used this platform to educate applicants on the importance of complying with the respective guidelines which would greatly improve the quality of the dossiers being submitted.

b. Increasing the number of Product Assessors

The Committee was informed that the number of members of staff conducting product assessments was not sufficient to effectively meet appreciable targets of evaluated product applications. To this effect, ZAMRA through its cooperating partner, USAID – CHEMONICS, engaged ten product assessors who helped increase the staffing levels thereby improving the output of product assessments.

Further, the Committee was informed that ZAMRA intended to engage part-time assessors who would help with the assessment of applications for human medicines to help clear the accumulated backlog and subsequently increase on the number of assessed product applications in the long run.

c. Planned Stakeholder Engagements – Training in Product Dossier Compilation

In order to increase awareness of the need for quality product dossier compilations and in-still an appreciable level of competence among the technical staff from the local pharmaceutical industry, ZAMRA had included in its 2024 Medium Term Budget Plan an activity dedicated to training industry in product dossier compilation for the sole purpose of equipping the industry with the basics of how to compile a product dossier for medicines focusing on vital information referenced to the many matters arising from the product assessments.

With the measures stated above, ZAMRA was expected to increase the number of product assessments done and product applications being recommended for approval.

Committee's Observations and Recommendations

The Committee observes with concern the failure by ZAMRA to evaluate 483 and 1,476 applications for MAs in 2020 and 2021 respectively due to low staffing levels.

The Committee further observes that delays in evaluating MAs may lead to medicine shortages and non-compliance. In this regard, the Committee recommends that ZAMRA should ensure that more staff are recruited in the MA section without further delay, as continued delay in the evaluation of the MAs may be a potential public health risk leading to unauthorised medicines on the Zambian market. Furthermore, in agreeing with stakeholders the Committee recommends that ZAMRA should streamline evaluation processes, utilise technology for faster assessments, and foster communication among staff.

3.2.2 Importation of Medicines

Stakeholders observed with concern that ZAMRA had only physical presence in three out of the forty-seven ports of entry, thereby weakening the monitoring aspect of imported medicines; posing a health risk due to counterfeit or sub-standard medicines entering the country without detection especially those which were being transported by buses and private vehicles.

Ministry's Response

The Committee was informed that where ZAMRA had no presence in the ports of entry, it collaborated with other Government agencies such as the Zambia Revenue Authority and the Drug Enforcement Commission in the regulation of the importation and exportation of medicines.

Further the Committee was informed that in an effort to strengthen the regulation of importation of medicines and allied substances, ZAMRA planned to promulgate a Statutory Instrument to designate selected ports of entry for medicines and allied substances in 2024. Once this SI was effected, it would limit ports of entry for medicines and allied substances which would allow ZAMRA to concentrate resources on those designated ports of entry.

Additionally, the Committee was informed that the Government of the Republic of Zambia had given a directive to decongest borders by reducing the number of agencies to only six. This move had affected ZAMRA such that they had no presence at Kazungula Port of entry even when an officer to be stationed there was recruited.

MoH also submitted that ZAMRA had intensified surveillance on the market to detect and take legal action including prosecution of those found dealing or selling illegal products to members of the public.

Committee's Observations and Recommendations

The Committee observes that the absence of ZAMRA in forty-four entry points posed a serious health risk to the public as illegal and substandard medicines may enter the country without detection. In this regard, the Committee recommends that ZAMRA should endeavour to be present at all entry points to enhance surveillance and not to compromise the quality of medicines entering the country, as collaborating agencies may not have the expertise required when it comes to medicines.

3.2.3 Registration of Retail Pharmacies, Health Shops, Wholesale Pharmacies, Public and Private Hospital Pharmacies

Stakeholders expressed concern that ZAMRA had not registered all premises operating as pharmacies in the country as some retail pharmacies and health shops operated without certificates of registration and health shop permits respectively.

Ministry's Response

The Committee was informed that ZAMRA in collaboration with stakeholders, had developed draft guidelines and standard of practice on the registration of hospital pharmacies, both public and private. However, there had been challenges in the registration of hospital pharmacies as they were still unresolved matters of overlap of functions with the Health Professions Council of Zambia (HPCZ). The Committee was further informed that a number of challenges and gaps had been identified during the time ZAMRA had been enforcing the Act. In this regard, the process of reviewing the Act had commenced and all the provisions in the Act that related to penalty units and imprisonment terms would be reviewed and made to be commensurate with the gravity of the offence and most importantly to serve as a deterrent.

The Committee was further informed that ZAMRA had been conducting operations to curb illegal outlets in collaboration with Zambia Police Service and Drug Enforcement Commission, resulting in a number of people being prosecuted for operating illegal outlets.

Committee's Observations and Recommendations

The Committee in noting the submission recommends that the conflicting pieces of legislation be harmonised without delay, so that the overlapping functions of ZAMRA and the HPCZ are resolved to facilitate the registration of public and private hospital pharmacies. Further, the Committee recommends that so as to deter people from operating without certificates of registration, the penalty should be stiff.

3.2.4 Monitoring of Medicines

Stakeholders submitted that despite ZAMRA having conducted inspections in eleven drug manufacturing companies, it had not fully enforced the Good Manufacturing Practice (GMP) guidelines as three drug manufacturing companies, were found wanting.

Stakeholders further expressed concern that twenty-five premises without certificates of registration were stocked with assorted authorised medicines which implied that the medicines were not procured from a duly registered distributor.

Ministry's Response

The MoH submitted that the conduct of GMP inspection was aimed at ensuring that medicines and allied substances manufactured by local manufacturing companies met the required standards of quality, safety and efficacy. The Committee was, however, informed that despite ZAMRA conducting inspections in eleven drug manufacturing

companies, it had not fully enforced the GMP guidelines. In this regard, ZAMRA was in the process of recruiting part time inspectors to increase on the number of inspectors, so as to strengthen post licensing surveillance inspections and increase on the compliance levels of registered outlets to the set standards. With the prevailing staffing levels, the concentration had been on the conduct of pre – licensing inspections which had significantly increased over time.

Committee's Observation and Recommendation

The Committee observes with concern that failure to strictly enforce compliance of GMP guidelines would compromise the quality of medicines being produced, thereby posing a health risk to the public. The Committee further observes that failure by ZAMRA to carry out post licensing inspections on some registered premises leads to non-compliance of the set pharmaceutical guidelines. In this regard, the Committee recommends that ZAMRA should ensure strict compliance of GMP and pharmaceutical guidelines, so as not to compromise the quality of medicines being produced.

3.2.5 Post Market Surveillance Activities

Stakeholders expressed concern that ZAMRA 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; However, ZAMRA 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 per cent.

Ministry's Response

The Committee was informed that the number of samples collected in 2019 were low due to inadequate human resources to conduct post market surveillance activities. Further, it was submitted that the low number of samples collected in 2020 was due to the travel restrictions during the COVID - 19 pandemic. However, ZAMRA had increased post licensing inspections and inspection of illegal stores operations to help identify counterfeit and sub-standard medicines which may be a danger to the end users. The MoH further submitted that ZAMRA had also been conducting routine and random sampling of medicines for quality testing and assessment of conformity to labelling requirements. In addition, the Committee was informed that ZAMRA had been analysing medicines using field screening tools such as mini lab test kits to ensure that only quality medicines were made available on the market.

Committee's Observations and Recommendations

The Committee in noting the submission recommends that ZAMRA should ensure that it meets the sampling targets to avoid sub-standard or falsified medical products circulating on the market, which may have a negative effect on public health. Further, the Committee reiterates the need for ZAMRA to recruit more staff for the effective discharge of their mandate.

3.2.6 Sensitisation on Importance of Observing Regulatory Requirements

Stakeholders expressed concern that despite ZAMRA's Annual Reports for 2019 to 2021 revealing that 98 per cent of the planned sensitisation activities were conducted through various platforms, only eight out of the 116 districts in the country were covered.

Ministry's Response

The Committee was informed that the low sensitisation coverage by ZAMRA was as a result of inadequate staffing levels in the implementing unit, and the effects of COVID - 19 that placed restrictions on travelling around the country to conduct sensitisation programmes. Further, lack of ZAMRA's presence in every part of the country posed a challenge in coordinating awareness activities in all provinces. In order to mitigate the above challenges, ZAMRA had employed one Public Relations Officer to beef up the Public Relations Unit which now had an establishment of two personnel.

The Committee was further informed that ZAMRA was implementing a decentralisation policy in a phased approach by opening new offices to cater for the provinces where it had no presence. The MoH further informed the Committee that ZAMRA had plans to conduct awareness programmes in all provinces in conjunction with community radio stations, starting with areas where they had no offices. Furthermore, the Committee was informed that ZAMRA was in the process of revising the communication and stakeholder engagement strategy in order to align it to stakeholder communication needs and in line with the Mission and vision of the 2022-2026 Strategic Plan.

Committee's Observations and Recommendations

The Committee observes with concern that only eight out of the 116 districts across the country were sensitised on the importance of observing regulatory requirements during the period under review. The Committee, therefore, recommends that sensitisation activities should cover the whole country if illegal operations are to be curbed and the public protected from consuming medicines which are not safe, efficacious and not of good quality.

3.2.7 Collaboration with Stakeholders

Stakeholders submitted that it was necessary for ZAMRA to sign Memorandum of Understanding (MoU) with Drug Enforcement Commission and Zambia Police Service for enhanced collaboration.

Ministry's Response

The Committee was informed that ZAMRA had started the process of engaging all the key stakeholders with the hope of signing MoUs in areas of common interest. In this regard, the Committee was further informed that ZAMRA was in the process of reviewing and strengthening the Communication and Stakeholder Engagement Strategy to enhance the institution's collaboration with its stakeholders by 31st December, 2023.

Committee's Observations and Recommendations

The Committee in noting the submission recommends that collaboration between ZAMRA and its stakeholders in the control and regulation of medicines should be strengthened. This will in turn strengthen the enforcement and hence, reduce the number of unauthorised and substandard medicines entering the country.

4.0 Conclusion

The Committee observes that the Government has through ZAMRA, put in place measures to control and regulate medicines, in the manufacturing, storage, importation, distribution and usage of medicines. However, implementation has been weak and not supported by enhanced enforcement for the protection of public health. In this regard, the Committee is of the view that ZAMRA should work with District Joint Operation Committees and Local Authorities to enhance enforcement. It is also the hope of the Committee that during the review process of both the National Drug Policy and the *Medicines and Allied Substances Act,* necessary policy and legal interventions are included to address the issues raised in the report.

Dr Christopher Kalila, MP
CHAIRPERSON

December, 2023
LUSAKA

APPENDIX I - National Assembly Officials

Mrs Doreen N C Mukwanka, Acting Director (SC)
Mrs Chitalu K Mumba, Deputy Director (SC)
Ms Betty Zulu, Acting Senior Committee Clerk (SC2)
Mrs Media Hachombwa-Mweele, Committee Clerk
Ms Catherine Chibuye, Administrative Assistant
Mr Daniel Lupiya, Committee Assistant

APPENDIX II- WITNESSES

Drug Enforcement Commission
Health Professionals Council of Zambia
Ministry of Health
National Airports Corporation
Office of the Auditor General
Pharmaceutical Society of Zambia
Zambia Medicines and Regulatory Authority
Zambia Police Service
Zambia Revenue Authority
Zambia Bureau of Standards