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Original Article

Regulatory Compliance Among Private Pharmaceutical Outlets in Three Regions of Tanzania

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ABSTRACT

Background: Regulatory compliance within pharmaceutical outlets is essential to ensure that medicines distributed to the public meet established standards of quality, safety, and efficacy. Private pharmaceutical outlets play a significant role in the distribution of medicines and healthcare delivery. This study aimed to assess regulatory compliance among private pharmaceutical outlets in three regions of Tanzania.

Materials and Methods: A retrospective cross-sectional study was conducted in May 2025 using secondary data extracted from inspection forms completed by the Pharmacy Council of Tanzania during routine regulatory inspections carried out between January and December 2024 in Dar es Salaam, Dodoma, and Mwanza. A multi-stage sampling approach was employed. An outlet was considered compliant if it met at least 10 out of the 12 selected regulatory compliance criteria.

Results: A total of 734 pharmaceutical outlets were assessed. Among these, 54.6% were ADDOs and 45.4% were pharmacies. Overall, 165 (22.5%) were reported to be compliant with the regulatory requirements. The highest compliance was observed in adequate lighting and ventilation 650 (88.6%). Other parameters compliance levels were: valid business permits 320 (43.6%), presence of expired medicines on the shelf (39.6%) of outlets, and presence of unregistered health products (30.4%). Pharmacies demonstrated significantly higher (28.5% vs 17.5%) overall regulatory compliance compared to ADDOs (OR = 1.89; CI: 1.32–2.68, $p<0.001$).

Conclusion: The regulatory compliance among private pharmaceutical outlets remains suboptimal. Pharmacies exhibited higher compliance compared to ADDOs. Strengthening regulatory enforcement, enhancing routine inspections, and providing continuous professional development are essential to improving compliance.

Keywords: Regulatory Compliance, Pharmacies, ADDOs, Pharmaceutical Outlets, Tanzania

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INTRODUCTION

Access to safe, effective, and quality medicines is a fundamental component of a functional health system [1]. Regulatory compliance within pharmaceutical outlets is essential to ensure that medicines distributed to the public meet established standards of quality, safety, and efficacy [2]. In many low- and middle-income countries (LMICs), including Tanzania, private pharmaceutical outlets play a significant role in the distribution of medicines and healthcare delivery [3]. However, weak adherence to regulatory requirements in such outlets may compromise public health through the circulation of substandard and falsified medicines, inappropriate dispensing practices, and poor storage conditions [4,5]. In Tanzania, pharmaceutical regulation has evolved considerably with the establishment of the Tanzania Medicines and Medical Devices Authority (TMDA), formerly known as the Tanzania Food and Drugs Authority (TFDA), and the Pharmacy Council [6]. These regulatory frameworks are intended to maintain high standards across the pharmaceutical supply chain. Recognizing the importance of regulating private medicine sellers, the Government of Tanzania, through the TFDA, established the Accredited Drug Dispensing Outlets (ADDOs) program in 2003 [7]. This innovative public-private initiative transformed previously unregulated "Part II Poisons Shops" into ADDOs staffed by trained dispensers operating under legally enforceable standards [8]. Regulatory compliance encompasses adherence to licensing requirements, good dispensing practices, proper storage conditions, record-keeping, and compliance with guidelines governing the handling and sale of medicines [9]. Non-compliance may arise from multiple factors, including inadequate knowledge of regulations, economic pressures, weak enforcement mechanisms, and limited routine inspections [2]. Private pharmaceutical outlets, including retail pharmacies and ADDOs, are critical access points for medicines in Tanzania [10]. However, studies in similar LMIC settings have reported widespread regulatory violations such as the unauthorized sale of prescription-only medicines, lack of qualified personnel, and poor adherence to storage standards [2,11]. These practices not only undermine regulatory objectives but also contribute to antimicrobial resistance, treatment failures, and increased healthcare costs [12,13].

Although Tanzania has made notable progress in strengthening its pharmaceutical regulatory capacity, there is limited evidence on the level of regulatory compliance among private pharmaceutical outlets across different regions. Furthermore, variations in compliance may exist due to differences in regulatory oversight, resource allocation, and socio-economic factors between regions. However, much of the available evidence in Tanzania has focused on specific aspects of pharmacy practice pharmaceutical outlets [7,8,10,13]. There remains limited evidence based on routine regulatory inspection data that simultaneously assesses multiple regulatory compliance indicators among both community pharmacies and ADDOs across geographically distinct regions. Understanding the magnitude of regulatory compliance is therefore crucial for policy decisions aimed at improving pharmaceutical service delivery. This study aimed to assess regulatory compliance among private pharmaceutical outlets in Dar es Salaam, Dodoma, and Mwanza regions of Tanzania. These regions were selected because they represent geographically and administratively distinct settings—the Eastern, Central, and Lake zones and have high pharmaceutical outlet numbers.

MATERIALS AND METHODS

Study Design, Setting, and Population

A retrospective cross-sectional study was conducted in May 2025 using secondary data extracted from inspection forms completed by the Pharmacy Council of Tanzania during routine regulatory inspections of private pharmaceutical outlets. The inspections were carried out between January and December 2024. The study was set in three geographically and administratively distinct regions of Tanzania: Dar es Salaam (Eastern Zone), Dodoma (Central Zone), and Mwanza (the Lake Zone). Data were accessed and reviewed at the Pharmacy Council's main regional offices located in each of the three regions.

The study population comprised all private pharmaceutical outlets, specifically, community pharmacies and ADDOs that were registered with the Pharmacy Council and underwent routine regulatory inspection between January and December 2024. Wholesale pharmacies were excluded from the study, as their operational and regulatory frameworks differ substantially from retail outlets. Additionally, pharmaceutical outlets with incomplete or missing data on key variables of interest were excluded to ensure data integrity and analytical validity.

Sample Size and Sampling Procedures

The sample size was determined using Yamane's (1967) formula for finite populations:

$$n = \frac{N}{1 + N(e)^2}$$

where n represents the required sample size, N is the population size, and e is the margin of error set at 0.05 for a 95% confidence level. Based on administrative records, an average of approximately 600 pharmaceutical outlet inspections are conducted annually per region by the Pharmacy Council:

$$n = \frac{600}{1 + 600(0.05)^2} = 240$$

Thus, sample of 240 pharmaceutical outlets was obtained per region, hence a total sample size of 720 outlets across the three regions. Therefore, the minimum total sample size was 720 outlets across the three regions. The final dataset contained 734 eligible inspection records, which were included in the analysis.

A multi-stage sampling approach was employed to ensure representativeness and minimize selection bias. First, stratified sampling was applied, with region (Dar es Salaam, Dodoma, Mwanza) and outlet type (pharmacy vs. ADDO) serving as strata. This ensured proportional representation of both outlet categories within each region. Second, within each stratum, simple random sampling was used to select individual inspection forms from the pool of all eligible inspections conducted during the study period. Equal proportions of pharmacy and ADDO inspection forms were targeted per region to allow balanced comparisons between the two outlet types**.**

Data Collection

Data were extracted from standardized Pharmacy Council inspection forms using a structured data collection tool. A total of twelve regulatory compliance indicators were selected to provide a comprehensive assessment of adherence to regulatory standards. These indicators covered key domains, including personnel qualifications, legal documentation, premises conditions, and medicine quality assurance.

The assessed parameters included: (i) presence of an authorized dispenser in ADDOs or a registered pharmacist/superintendent and supporting pharmaceutical personnel in pharmacies; (ii) validity of professional licenses or dispensing certificates; (iii) use of clinical coats; (iv) availability of a valid premises registration certificate; (v) possession of a valid business permit; (vi) proper display of certificates and permits; (vii) cleanliness of the facility; (viii) absence of unregistered health products; (ix) absence of expired medicines on shelves; (x) availability and proper use of a dispensing register; (xi) adequacy of lighting and ventilation; and (xii) availability of functional cooling appliances (e.g., fan or air conditioning).

Each outlet was assessed against these indicators and categorized as either compliant or non-compliant. An outlet was considered compliant if it met at least 10 out of the 12 selected regulatory compliance criteria. Twelve regulatory compliance indicators were assessed based on the items available in the Pharmacy Council inspection forms. For the purpose of this study, an outlet was classified as having overall regulatory compliance if it met at least 10 of the 12 indicators, equivalent to a minimum compliance level of 83.3%. This threshold represents substantial adherence across the selected regulatory domains.

Data Analysis

Data were entered and cleaned in Microsoft Excel before being exported to STATA version 15 (Stata Corp, College Station, TX) for further analysis. In the statistical analysis, frequencies and percentages were calculated. The results were presented in frequency distribution tables and figures. To examine the association between outlet type (pharmacy vs. ADDO) and regulatory compliance, logistic regression analysis was performed. Univariate logistic regression was conducted for each compliance parameter individually, with ADDOs serving as the reference category. Results were reported as odds ratios (OR) with corresponding 95% confidence intervals (CI). A p-value of less than 0.05 was considered statistically significant for all analyses.

RESULTS

A total of 734 pharmaceutical outlets were assessed, comprising 264 (36.0%) from Dar es Salaam, 222 (30.3%) from Dodoma, and 248 (33.7%) from Mwanza. Among these, 54.6% were ADDOs and 45.4% were pharmacies. Overall, 165 (22.5%) were reported to be compliant with the regulatory requirements. Table 1 presents pharmaceutical outlets' compliance across various regulatory parameters. The highest compliance was observed in adequate lighting and ventilation 650 (88.6%), followed by cleanliness of facilities 607 (82.7%) and availability of cooling appliances 605 (82.4%). In contrast, lower compliance was noted in the presence of valid business permits 320 (43.6%), use of clinical coats 353 (48.1%), and display of certificates 368 (50.1%). Additionally, the concerning findings included the presence of expired medicines in 291 (39.6%) of outlets and unregistered health products in 223 (30.4%) of outlets.

Table 1: Pharmaceutical Outlets' Compliance Across Various Regulatory Parameters (N=734)

S/N	Parameter	Frequency (n)	Percent (%)
1	Presence of authorized dispenser/ superintendent/ authorized personnel	457	62.3
2	Valid and updated license to practice/dispensing certificate	412	56.1
3	Clinical coats	353	48.1
4	Presence of a valid premises registration certificate	395	53.8
5	Presence of a valid business permit	320	43.6
6	Displayed certificates and business permits	368	50.1
7	Cleanliness of the facility	607	82.7
8	Presence of unregistered health products	223	30.4
9	Presence of expired medicine on the shelf	291	39.6
10	Presence and usability of the dispensing register	423	57.6
11	Adequate lighting and ventilation	650	88.6
12	Provision of cooling appliance (Fan/AC)	605	82.4

Figure 1 illustrates regional variations in regulatory compliance among three regions. Mwanza was reported to have a higher level of regulatory compliance, i.e., 79 (31.9%).

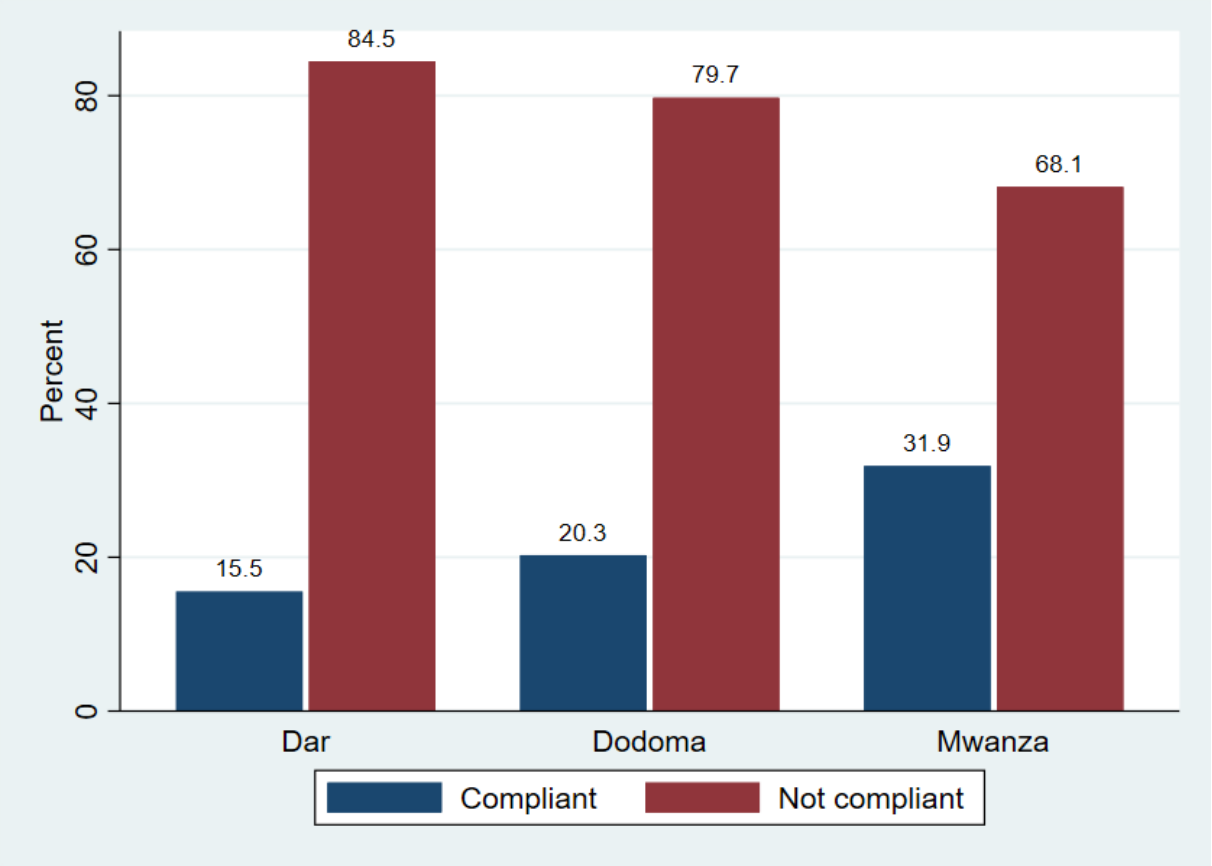


Figure 1: Percentage Distribution of Compliance Status Across Region

Figure 2 shows regulatory compliance by pharmaceutical outlet category. Pharmacies were reported to have higher regulatory compliance, 95 (28.5%), compared to ADDOs, 70 (17.5%).

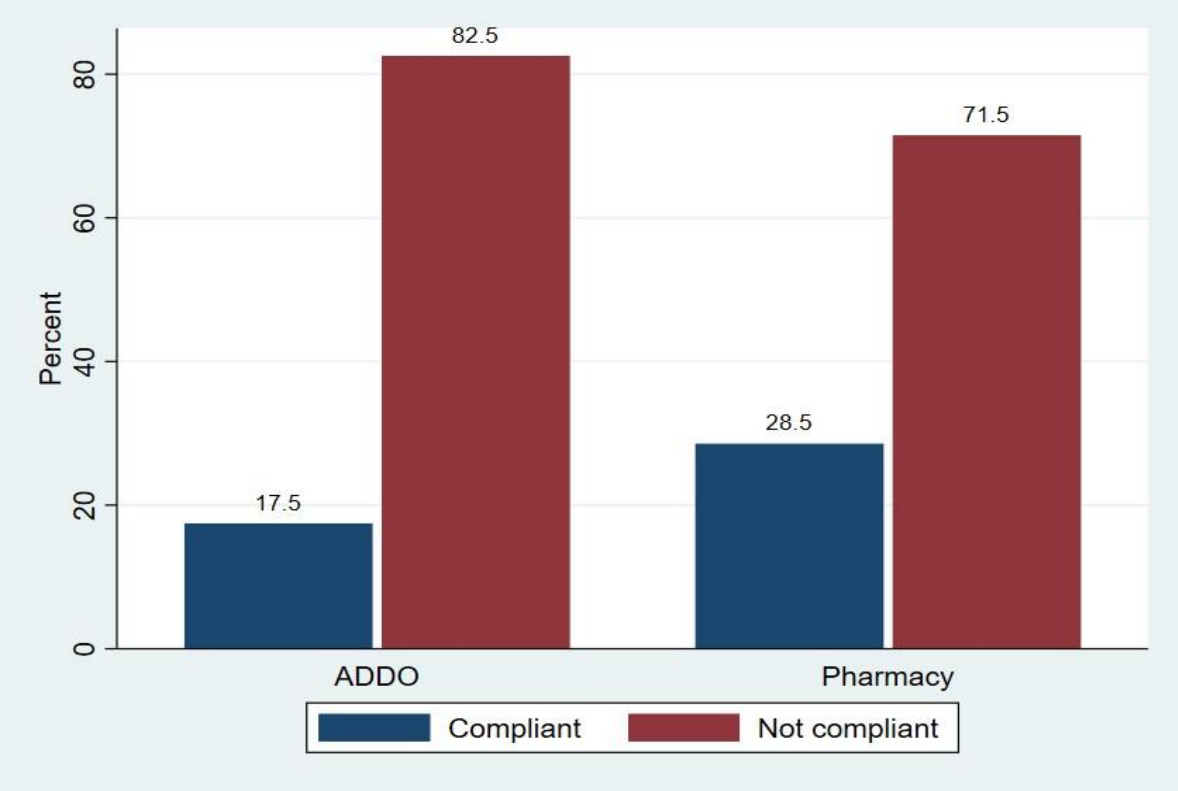


Figure 2: Regulatory Compliance by Pharmaceutical Outlet Category

Table 2 summarizes the univariate logistic regression analysis examining the association between regulatory compliance parameters and outlet type (ADDO vs. Pharmacy). Pharmacies demonstrated significantly higher overall regulatory compliance compared to ADDOs (OR = 1.89; CI: 1.32–2.68). Across nearly all individual parameters, pharmacies had significantly greater odds of compliance than ADDOs. The strongest associations were observed for provision of a cooling appliance (OR = 11.02; CI: 5.96–20.39), displayed certificates and business permits (OR = 4.59; CI: 3.36–6.28), presence of an authorized dispenser (OR = 4.49; CI: 3.21–6.27), adequate lighting and ventilation (OR = 4.41; CI: 2.47–7.86) and presence of a valid premises registration certificate (OR= 3.80; CI: 2.78 – 5.18) Notably, pharmacies were more likely to have expired medicines on shelves than ADDOs (OR = 1.70; CI: 1.26–2.29; p = 0.001). However, the presence of unregistered health products was higher in pharmacies, although the difference was not statistically significant (OR = 1.29; CI: 0.94–1.77; p = 0.113).

Table 2: Univariate Analysis for the Association of Regulatory Compliance and Independent Variables Between ADDO and Pharmacies

Parameter	ADDO (N=401), n (%)	Pharmacies (N=333), n (%)	*OR (95%CI)	P-Value
Overall regulatory compliance	70 (17.5)	95 (28.5)	1.89 (1.32 - 2.68)	<0.001
Presence of authorized dispenser/ superintendent/ authorized personnel	190 (47.4)	267 (80.2)	4.49 (3.21 - 6.27)	<0.001
Valid and updated license to practice/dispensing certificate	171 (42.6)	241 (72.4)	3.52 (2.58 – 4.81)	<0.001
Clinical coats	160 (39.9)	193 (58.0)	2.08 (1.54 – 2.79)	<0.001
Presence of a valid premises registration certificate	158 (39.4)	237 (71.2)	3.80 (2.78 – 5.18)	<0.001
Presence of a valid business permit	146 (36.4)	174 (52.3)	1.91 (1.42 – 2.57)	<0.001
Displayed certificates and business permits	135 (33.7)	233 (70.0)	4.59 (3.36 – 6.280	<0.001
Cleanliness of the facility	310 (77.3)	297 (89.2)	2.42 (1.59 – 3.68)	<0.001
Presence of unregistered health products	112 (27.9)	111 (33.3)	1.29 (0.94 – 1.77)	0.113
Presence of expired medicine on the shelf	136 (33.9)	155 (46.5)	1.70 (1.26 – 2.29)	0.001
Presence and usability of the dispensing register	193 (48.1)	230 (69.1)	2.41 (1.77 – 3.26)	<0.001
Adequate lighting and ventilation	332 (82.8)	318 (95.5)	4.41 (2.47 – 7.86)	<0.001
Provision of cooling appliance (Fan/AC)	284 (70.8)	321 (96.4)	11.02(5.96 – 20.39)	<0.001
Presence of authorized dispenser/ superintendent/ authorized personnel	190 (47.4)	267 (80.2)	4.49 (3.21 - 6.27)	<0.001
Valid and updated license to practice/dispensing certificate	171 (42.6)	241 (72.4)	3.52 (2.58 – 4.81)	<0.001
Clinical coats	160 (39.9)	193 (58.0)	2.08 (1.54 – 2.79)	<0.001
Presence of a valid premises registration certificate	158 (39.4)	237 (71.2)	3.80 (2.78 – 5.18)	<0.001

**ADDO was the reference in logistic regression*

DISCUSSION

This study assessed regulatory compliance among private pharmaceutical outlets in three regions of Tanzania using routine inspection data. Overall, the findings indicate a relatively low level of compliance, with only 22.5% of outlets meeting the predefined regulatory threshold. This suggests substantial gaps in adherence to regulatory standards, despite Tanzania's established regulatory framework. These findings highlight persistent challenges in ensuring the quality of pharmaceutical services in private-sector outlets. The overall compliance level observed in this study is consistent with findings from other low- and middle-income countries, where regulatory enforcement in private pharmaceutical sectors remains suboptimal [2,10,11,14,15]. Weak compliance has often been attributed to limited regulatory capacity, inadequate supervision, and economic incentives that may encourage non-adherence to standards [16,17].

Notably, pharmacies demonstrated significantly higher overall compliance than ADDOs (28.5% vs. 17.5%, $p < 0.001$), a finding consistent with previous studies from Tanzania and other sub-Saharan African countries, where pharmacies typically benefit from more rigorous initial licensing requirements, higher staffing qualifications, and more frequent supervisory oversight [18-20]. Since its establishment in 2003, the ADDO program's goal has been to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural or peri-urban areas with few or no registered pharmacies [8]. However, regulatory infringements in ADDOs have consistently been reported in various studies [13,21-23]. Therefore, it is encouraged that ADDOs operate in rural areas with limited access to pharmaceutical services rather than in urban and peri-urban areas with a significant number of pharmacies.

Compliance varied substantially across regulatory indicators, with higher adherence observed in structural and environmental parameters such as lighting and ventilation, cleanliness, and availability of cooling appliances. The infrastructural requirements might have higher compliance because they are easier to implement and are visibly assessed during inspections [5]. In contrast, professional and administrative indicators such as licensing, documentation, and display of certificates had markedly lower compliance. This suggests that while outlets may invest in visible infrastructure, less attention is given to regulatory documentation and professional standards, which are equally critical for accountability and quality assurance [9,24]. Of particular concern is the substantial proportion of outlets with expired medicines (39.6%) and unregistered health products (30.4%). These findings are consistent with earlier reports indicating that inadequate regulatory compliance contributes to the circulation of substandard and potentially harmful medicines in retail outlets [25]. However, these findings are higher than those reported in a study conducted in Nepal that revealed 25.3% of pharmaceutical outlets had expired medicines not in separate shelves, and/or designated places, and only 7.1% were found storing unregistered medicines [15]. Regional variations in compliance were observed, with Mwanza demonstrating relatively higher compliance levels compared to Dar es Salaam and Dodoma. Similar geographic disparities have been reported in previous studies, where proximity to regulatory authorities and urban centers influenced compliance levels [11,15]. The outlets closer to administrative centers are subjected to more frequent inspections and tend to exhibit better compliance.

In this study, pharmacies demonstrated higher performance across most regulatory parameters, including staffing, licensing, documentation, and infrastructure. This is likely due to stricter regulatory requirements for pharmacies, including the mandatory presence of a superintendent registered pharmacist and other pharmaceutical personnel, i.e., a pharmaceutical technician, a pharmaceutical assistant, [26] as well as better access to resources. In contrast, ADDOs, which are designed to improve access to essential medicines in underserved areas, may face challenges such as limited training [27], financial constraints and weaker supervision. However, in this study, pharmacies were more likely than ADDOs to have expired medicines on their shelves. This contradictory finding may reflect higher stock volumes and a wider range of products in pharmacies, increasing the risk of poor inventory management [28,29]. It may also indicate gaps in stock rotation practices within these outlets. This highlights the need for strengthening inventory management practices even in higher-level facilities.

Overall, the findings emphasize the need for strengthened regulatory enforcement, continuous professional training, and supportive supervision to improve compliance. Interventions such as

regular inspections, capacity-building programs, and the use of digital monitoring systems may enhance adherence to regulatory standards. Additionally, customized strategies targeting ADDOs may be necessary to address their unique challenges and ensure equitable quality of pharmaceutical services across outlet types.

STRENGTHS AND LIMITATIONS

This study has several strengths that enhance the validity and relevance of its findings. First, the study utilized a relatively large sample size of pharmaceutical outlets across three geographically diverse regions of Tanzania, thus increasing the generalizability of the results to similar settings within the country. Second, the use of routine inspection data collected by the Pharmacy Council of Tanzania enhances the reliability and objectivity of the measurements. Unlike self-reported data, inspection-based assessments reduce the risk of social desirability bias and provide a more accurate reflection of actual practices within pharmaceutical outlets. However, this study has several limitations. First, the use of a retrospective cross-sectional design based on secondary data limits the ability to establish causal relationships between variables. Second, the analysis was restricted to variables available in the inspection forms, which may not capture all relevant aspects of regulatory compliance, such as dispensing practices, patient counseling, or economic factors influencing compliance. Third, regulatory authorities such as the Pharmacy Council are more likely to prioritize inspections of pharmaceutical outlets for which there is prior information or suspicion of non-compliance with established regulatory standards. Finally, the use of univariate logistic regression does not account for potential confounding factors, which may influence the observed associations between outlet type and regulatory compliance.

CONCLUSION

This study demonstrates that regulatory compliance among private pharmaceutical outlets remains suboptimal, with significant gaps in critical areas such as licensing, documentation, and quality assurance of medicines. Pharmacies exhibited higher compliance compared to ADDOs. Strengthening regulatory enforcement, enhancing routine inspections, and providing continuous professional development are essential to improving compliance. Policymakers and regulatory authorities should prioritize context-specific strategies, including supportive supervision and capacity-building initiatives, to ensure that all pharmaceutical outlets consistently meet established standards and contribute to safe and effective healthcare delivery in Tanzania.

DECLARATIONS

Ethical Approval: The study obtained ethical approval from the Joint Catholic University of Health and Allied Sciences (CUHAS) and Bugando Medical Centre (BMC) Research and Ethics Review Committee, with permits No.3534/2025, 3557/2025, and 3550/2025 approved on 16th April 2025. The ethics committee waived the requirement for participant informed consent because the study used secondary data.

Informed Consent: Written informed consent was obtained from all participants prior to data collection.

Consent for Publication: Not applicable.

Conflict of Interest: The authors declare no conflict of interest.

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Authors' Contributions: Conceptualization and study design: SM, VS, EE, GM. Methodology, resources, and data collection: VS, EE, GM, DK, JM, CK, PN. Data analysis: SM, SZ, GN, BM. Writing the original draft: SM. Review and editing: All authors.

Data Availability: The datasets generated and analyzed during this study are not publicly available due to ethical and confidentiality restrictions. However, they may be obtained from the corresponding author upon reasonable request, subject to approval by the relevant ethics committee.

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