OPERATIONS RESEARCH SOCIETY OF EAST AFRICA JOURNAL

2026 vol 16, No. 1
https://doi.org/10.56279/orseaj.v16i1.8

ORSEA Journal

Research Article

ORSEA, 16, 1
94

Regulatory Frameworks and Enterprise Growth: A Study of Medium-Sized Pharmaceuticals in Tanzania

Fred P. Okangi[1] and Theresia E. Busagara[1]*

1 *University of Dar es salaam Business School- Tanzania.*

* ***Correspondence:*** okangifred@gmail.com

Abstract

The study examined how regulatory frameworks specifically tax regulations, licensing requirements, labour laws, and safety regulations affect the growth medium-sized pharmaceutical enterprises in Tanzania. Data were collected from 108 enterprises randomly selected from Ilala Municipal in Dar es Salaam. Using Partial Least Squares Structural Equation Modelling (PLS-SEM) data were analysed and the study found that tax regulations, licensing requirements, and labour laws have significant positive effects on growth of enterprises ($p<0.05$), while safety regulations have an insignificant effect. These findings suggest that regulatory frameworks can facilitate growth when streamlined. Thus, the study suggests that policymakers should streamline regulatory frameworks to minimise compliance costs while supporting enterprise growth.

Keywords: Green ICT practices, Norm Activation Theory, Intention to Adopt, Higher Learning Institutions, Tanzania

Received: 25 August 2025
Revised: 21 December 2025
Accepted: 03 April 2026
Published: 27 April 2026

Citation: Okangi. F. & Busagara. T. (2026). Regulatory Frameworks and Enterprise Growth: A Study of Medium-Sized Pharmaceuticals in Tanzania. *ORSEA Journal, 16*(1), 94–108. https://doi.org/10.56279/orseaj.v16i1.8

Copyright: © 2026, University of Dar es Salaam.

This is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY-NC-ND 4.0) license.

Introduction

The regulatory framework is a system of rules, guidelines, and institutions established by governments to ensure compliance and protect public interests within a specific industry or sector (Agu et al., 2023). While there is a push for international harmonisation of regulations to streamline processes and reduce duplication of efforts (Matsuda, 2019), challenges persist due to varying regulatory standards and capacities of national agencies, leading to duplication, redundancy, and potential harm to public health (Gostin et al., 2020). While regulations can pose cost impacts, they can also provide competitive advantages and support growth, highlighting a nuanced relationship between regulations and business growth (Peck et al., 2015). Global analyses across countries emphasise the significant link between business regulations, firm creation, and economic growth, underscoring the importance of sound regulatory practices for driving business expansion and overall economic development. Thus, the regulatory framework significantly affects the growth of firms, including medium-sized pharmaceutical enterprises at a global level (Divanbeigi & Ramalho, 2022).

The legal and regulatory environment influences factors such as business registration, licensing requirements, land acquisition procedures, and investment policies. Inadequate regulations can lead to complexities in starting and expanding pharmaceutical businesses, hindering their growth potential (Pazi, 2020). The complexity and stringency of these regulations can have significant impacts on operational efficiency, cost structures, and market entry strategies for the pharmaceutical firms. Issues such as compliance with Good Manufacturing Practices (GMP), registration and licensing requirements, and adherence to quality standards are critical areas where regulatory policies intersect with business operations. While these regulations are essential for ensuring the safety and efficacy of pharmaceutical products, they can also impose substantial administrative and financial burdens on medium enterprises, potentially stifling growth (Macha & Mtei, 2022).

In Tanzania, the regulatory framework significantly impacts the growth of enterprises, including medium-sized pharmaceutical businesses. As a result, the Tanzanian Government has implemented several initiatives aimed at enhancing the performance of pharmaceutical enterprises. Key efforts include the establishment of the National Medicines Policy, which outlines strategies for ensuring the availability and accessibility of essential medicines while promoting local manufacturing (Fimbo et al., 2024). Additionally, the government has initiated the Pharmaceutical Sector Action Plan (PSAP) 2020, which focuses on improving logistics management, data accuracy through electronic systems, and capacity building for local councils in pharmaceutical services (Sangeda et al., 2024). The government also encourages private sector engagement by facilitating industrial parks for pharmaceutical production and providing fiscal incentives. These measures are designed to strengthen the overall pharmaceutical supply chain, improve product quality, and enhance the operational environment for pharmaceutical enterprises in Tanzania (Fimbo et al., 2024).

Furthermore, the government of Tanzania has established the regulatory framework for pharmaceutical enterprises, which is primarily governed by the Tanzania Medicines and Medical Devices Authority (TMDA), which operates under the Tanzania Medicines and Medical Devices Act, Cap 219. This act mandates the TMDA to ensure the quality, safety, and effectiveness of medicines and medical devices

(TMDA, 2021). Key regulations include licensing requirements for manufacturers and distributors, which necessitate obtaining a Business Permit and a Product Registration Certificate after compliance with safety standards. Additionally, tax regulations apply, including exemptions for certain entities under the TMDA Act. The framework also encompasses employment and labour laws, ensuring fair labour practices within the pharmaceutical sector, and safety regulations that govern workplace conditions to protect employees and consumers alike (Rutta et al., 2021). This regulatory context sets the stage for understanding how previous studies examine its effect into enterprise growth

As such, previous research indicates that regulatory compliance poses an inconsistent burden on SMEs (Chukwudi et al. 2015; Udo, 2024; Francisco et al., 2023), whereas pharmaceutical enterprise growth has largely examined either small firms or the broad SME category, without isolating medium-sized firms (Agu et al., 2023; Matsuda, 2019; and Sangeda et al., 2024). They often fail to differentiate how various regulatory domains (tax, safety, and labour) uniquely affect medium-sized enterprises. Notably, studies in Tanzania's pharmaceutical sector have not explicitly focused on medium-sized enterprises, treating the SME sector as a homogenous group. Similarly, World Bank Doing Business reports and OECD studies have documented that smaller firms face higher relative costs to meet regulations, which can impede their growth. This leaves an open question: how do regulatory frameworks affect medium-sized pharmaceutical firms differently from small or large firms? The study then focuses on medium-sized enterprises is partly motivated by such evidence, as medium firms often indicate the line between the flexibility of small businesses and the complex compliance of large firms.

This study addresses that gap by examining medium-sized firms separately, thereby contributing new insight to Tanzania-specific literature. Therefore, this study aims to: (1) Assess the effect of tax regulations on the growth of medium-sized pharmaceutical enterprises in Tanzania; (2) Determine the influence of licensing requirements on enterprise growth; (3) Examine the influence of labour laws on growth; (4) Evaluate the effect of safety regulations on enterprise growth. Understanding these relationships is crucial for policymakers, as medium-sized pharmaceutical firms are key to Tanzania's healthcare supply chain. Insights from this study can inform regulatory reforms to foster growth in this vital sector. Furthermore, the divergent effect of compliance may be explained by Institutional theory explaining how organizations respond to external pressures, particularly in regulated environments Firms with stronger ability to handle external pressure might leverage compliance to gain legitimacy and a competitive advantage, whereas institutional capabilities constrained firms experience regulations purely as costs. Integrating institutional theory thus helps explain why some enterprises perceive regulatory frameworks as burdensome while others can turn compliance into a strategic advantage.

Literature Review

Theoretical Review

Institutional theory suggests that organizations operate within broader legal and social systems known as rules, norms, and beliefs within which they operate and must conform to these external requirements and gain legitimacy and access critical resources (DiMaggio & Powell, 1983; Scott, 2008). Researchers in the field of organizational change have utilized institutional theory to explain how organizations adopt new practices not necessarily because they are efficient, but because they are perceived as legitimate within their institutional context (Aksom & Tymchenko, 2020). In the pharmaceutical sector, regulatory institutions such as TMDA exert coercive pressures through formal requirements, taxes, licensing, labour, and safety standards that shape firm behavior. Compliance with these regulations is often essential for market access and organizational legitimacy (Meyer & Rowan, 1977). The theory further account for the dual role of regulation: while it may impose compliance burdens that hinder flexibility or growth, it can also support firms by enhancing credibility, improving operational standards, and enabling access to formal markets (Oliver, 1991). Prior research supports this view, showing that effective regulation can encourage innovation and strategic adaptation (Sinha & Kesselheim, 2022; Um et al., 2023). Thus, institutional theory provides a useful lens to explore how medium-sized pharmaceutical firms in Tanzania respond to regulatory frameworks and how these responses affect their growth.

Empirical Findings

Empirical research suggests that regulatory frameworks, principally tax-related, can considerably influence business success. For example, changes such as corporate tax reductions have been shown to enhance profitability and stimulate domestic growth, especially when accompanied by policies that incentivize capital repatriation and reinvestment in research and development (Sinha & Kesselheim, 2022). These dynamics were evident in the U.S. pharmaceutical sector, where reduced corporate taxes encouraged innovation and expansion, particularly among mid-sized enterprises. Similarly, licensing frameworks remain crucial for maintaining safety and quality standards, where licensing and product registration are often complex and time-consuming (Um et al., 2023; Sinha & Kesselheim, 2022). Such regulatory delays may reduce the competitive edge of smaller firms, although in some cases, well-structured licensing regimes have fostered growth and innovation by clarifying operational expectations and reducing market risks (Mallett et al., 2022).

Labour regulations also exhibit dual effects. On one hand, overly rigid employment laws may limit hiring

flexibility and increase operational costs, particularly in highly regulated and capital-sensitive sectors. On the other hand, supportive labour policies that promote workforce stability, skills development, and fair practices, can enhance productivity and reduce turnover, contributing positively to long-term growth (Sinha & Kesselheim, 2022; Sharma, 2019). This duality is reflected in studies across multiple jurisdictions, including India, the United Kingdom, and Tanzania, where firms reported both constraints and advantages arising from labour-related compliance (Mallett et al., 2022). In addition, safety regulations, as they try to protect employees and consumers, instead have shown mixed effects on enterprise growth. In contexts where the cost of compliance is excessively high relative to firm size and resources, such regulations may serve as barriers to scaling, particularly for medium-sized enterprises (Sharma, 2019). However, when integrated into broader risk management frameworks, safety regulations can enhance consumer trust, improve workplace efficiency, and reduce operational hazards, factors that support sustainable growth over time (Nwoke, 2024).

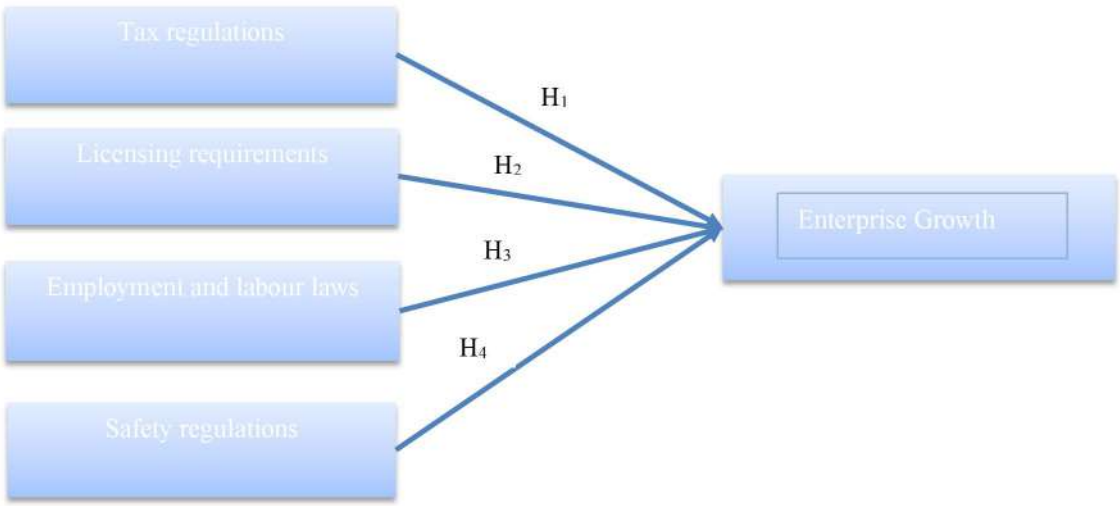
Regional evidence shows that regulatory harmonisation efforts, such as the EAC-MRH initiative, can improve efficiency, reduce duplication, and enhance institutional capacity (Ngum et al., 2025). While harmonised inspection and registration systems have strengthened regulatory trust, their direct influence on firm-level outcomes, particularly among medium-sized enterprises, remains insufficiently studied. Persistent regulatory capacity gaps in East Africa (Ndomondo-Sigonda et al., 2021a) and similar challenges across SSA (Agu et al., 2023) highlight the broader regional nature of these constraints. The Kenya Pharmaceutical Industry Diagnostic Report (2020) similarly notes governance fragmentation and weak enforcement, despite supportive policy frameworks. Recent findings further link high compliance and tax burdens to limited SME expansion and reduced reinvestment capacity (Besigomwe, 2024; Chukwudi et al., 2023), suggesting that harder regulatory environments may negatively affect SME growth and new business formation.

Evidence from global and regional studies shows that the influence of regulatory compliance on business growth is context-dependent, shaped by regulatory design, enforcement consistency, firm size, industry characteristics, and the broader business environment. However, most research has focused on either large pharmaceutical firms or micro-enterprises, leaving medium-sized firms, particularly in low and middle-income countries such as Tanzania, underrepresented in the literature. This study addresses that gap by examining how tax regulations, licensing requirements, labour laws, and safety regulations affect the growth of medium-sized pharmaceutical enterprises in Tanzania. Existing studies offer useful insights but highlight omissions: Um et al. (2022) analysed patent and GMP regulation but overlooked taxation and licensing, while Pezzola and Sweet (2022) focused on market standardisation without considering labour and safety laws. Although regulation is linked to innovation and standardisation, its broader implications for enterprise growth in developing contexts remain insufficiently examined.

Conceptual framework and hypotheses development

A conceptual framework guides the study by linking the theoretical foundation to research objectives and methods, helping to structure and analyse the research problem (Miles et al., 2014). This study outlines the relationships among key variables and informs hypothesis development. As shown in Figure1, tax regulations, licensing requirements, labour laws, and safety regulations are the independent variables, while the growth of medium-sized pharmaceutical enterprises is the dependent variable.

Figure 1: A Conceptual Framework



Source: Researcher's Constructed (2024)

Based on the literature review provided and the conceptual framework (Figure 1), which illustrates the relationship between the independent and the dependent variables, the following hypotheses were developed and tested:

***H*$_1$:** *Tax regulations positively influence enterprise growth.*
***H*$_2$:** *Licensing requirements positively influence enterprise growth.*
***H*$_3$:** *Employment and labor laws positively influence enterprise growth.*
***H*$_4$:** *Safety regulations positively influence to enterprise growth.*

Methods

The study was conducted in Dar es Salaam, Ilala Municipal, a major commercial hub in Tanzania with significant concentration of medium-sized pharmaceutical enterprise practitioners (Fimbo et al., 2024). Data were collected through survey by the use of a structured questionnaire. The sampling frame was obtained from the Tanzania Medicines and Medical Services Authority (TMDA registry, 2024) listing medium-sized pharmaceutical enterprises in Dar es Salaam as defined in the SMEs Policy 2003. A simple random sampling technique was used: we assigned numbers to 150 listed enterprises and used a random number generator to select 120, of which 108 responded (90% response rate). Each regulatory construct (Tax, Licensing, Labour, and Safety) was measured with at least 4 items using a 5-point Likert scale from Strongly Disagree to Strongly Agree. Enterprise growth (EG) of the firms was measured using the increase over the past three years. All items were adapted from established scales in the literature (Peck at al., 2018; Sjögrén & Syrjä, 2015) and refined to the Tanzanian context.

The sample of 108 firms exceeds the minimum recommended size for PLS-SEM based on the 10-times rule (10 times the number of indicators or paths per construct) and was deemed adequate for detecting medium effect sizes with a power of 0.80 (Cohen et al., 2018). A power analysis indicates that with 108 cases and our model structure, we have an approximate power of 0.85 to detect R^2 of 0.15 at α=0.05.”). PLS-SEM was chosen for its robustness with smaller samples and complex models. Although 108 responses were collected, which meets the 10-times rule for our model the study acknowledge that this is a modest sample. A post-hoc power analysis shows the sample is adequate for detecting moderate effect sizes, but smaller effects might go undetected. The significance of path coefficients was tested via bootstrapping with 5,000 resamples (two-tailed test, 95% confidence intervals). All constructs were modelled as reflective indicators, justified by the fact that the items are manifestations of the underlying construct (Hair et al., 2021). Harman’s single-factor test was used to assess common method bias and no severe common method variance was detected. Additionally, the study applied the full collinearity approach in PLS (Castillo et al,, 2026) and found all variance inflation factors (VIFs) were below 3 which indicate no multicollinearity problem exists. All ethical approvals were conducted including seeking participants consent by informing them about the study. Participation was voluntary and responses were kept confidential.

Results

Measurement and Structural Models Analysis

The examination of measurement and structural models in Partial Least Squares Structural Equation Modelling (PLS-SEM) focuses on two key components: measurement models and structural models as provided below.

Indicator Reliability Analysis for the Measurement Model

Indicator Reliability Analysis for the Measurement Model in PLS-SEM is a crucial step that assesses how effectively each indicator reflects its corresponding latent construct. In this study, reflective models were employed, focusing on indicator loadings greater than 0.7, as recommended by Rasoolimanesh (2022), and Hair et al. (2021). Table 1 presents the accepted indicators based on their outer loadings, with many exceeding the 0.70 threshold suggested by Zait and Bertea (2021). Additionally, indicators with loadings between 0.5 and 0.7 were retained due to their potential acceptability, while those below 0.4 were excluded for being inadequate. This approach ensures that the measurement model maintains a high level of reliability, allowing for valid interpretations of the structural relationships in the subsequent analysis.

Table 1: Indicator Outer Loadings

Code	Tax regulations	Licensing requirements	Employment and labor laws	Safety regulations	Growth of medium enterprises
TAR1	0.811				
TAR2	0.831				
TAR4	0.558				
TAR5	0.795				
TAR7	0.652				
LCR2		0.913			
LCR3		0.949			
LCR5		0.956			
LCR6		0.504			
ELL1			0.544		
ELL2			0.832		
ELL3			0.845		
ELL4			0.847		
ELL5			0.827		
SFR1				0.809	
SFR2				0.827	
SFR3				0.758	
SFR4				0.848	
SFR5				0.765	
SFR6				0.645	
EG1					0.525
EG2					0.842
EG3					0.851
EG4					0.765

Source: Field data (2024)

Internal Consistency Reliability Analysis for the Measurement Model

Following the Indicator Reliability Analysis, the study proceeded to evaluate the Internal Consistency Reliability Analysis for the Measurement Model. This step is crucial in PLS-SEM, as it verifies the reliability of constructs by examining how well indicators measuring the same construct are correlated. The study utilized Cronbach's alpha, Rho_A, and composite reliability to assess internal consistency, in line with the recommendations of Sosthenes et al. (2022). Acceptable reliability values start at 0.7, with those between 0.7 and 0.9 considered satisfactory (Rasoolimanesh, 2022). The results in Table 2 indicates that all three measures exceeded the minimum threshold of 0.70, confirming that the measurement model effectively captures the intended constructs and produces valid results.

Table 2: Construct Reliability and Validity

Construct	Cronbach's Alpha	Reliability Coefficients (Rho_A)	Composite Reliability (Rho_C)	AVE
Tax regulations	0.708	0.838	0.760	0.568
Licensing requirements	0.721	0.864	0.796	0.512
Employment and labor laws	0.744	0.760	0.881	0.663
Safety regulations	0.703	0.891	0.790	0.502
Enterprise Growth	0.734	0.788	0.789	0.545

(Source: Field Data, 2024)

Validity Assessment for the Measurement Model

After evaluating the reliability of the measurement model, the study proceeded to assess its validity. Validity Assessment for the Measurement Model in PLS-SEM is an essential step that confirms whether the constructs accurately reflect the intended theoretical concepts. This evaluation typically involves examining both convergent validity and discriminant validity. A robust measurement model demonstrates high convergent validity and adequate discriminant validity, ensuring that the constructs are reliable and effectively represent the underlying theoretical framework (Hair et al., 2021; Sosthenes et al., 2022). This comprehensive evaluation is crucial for drawing valid inferences from the structural relationships analyzed in PLS-SEM.

Discriminant Validity Analysis for the Measurement Model

Discriminant Validity Analysis typically employs two primary methods: the Fornell-Larcker criterion and the Heterotrait-Monotrait (HTMT) ratio. The Fornell-Larcker criterion compares the square root of the Average Variance Extracted (AVE) for each construct with its correlations to other constructs; to establish discriminant validity, a construct's AVE must be greater than its correlations with other constructs. However, this method can sometimes yield ambiguous results, particularly in empirical studies where constructs may exhibit similar loadings (Wang et al., 2023). Therefore, the HTMT ratio is often recommended as a more reliable alternative, with thresholds set at 0.85 for conceptually distinct constructs and 0.90 for similar constructs (Köhler & Hartig, 2019). Values that exceed these thresholds indicate potential overlap between constructs, suggesting that discriminant validity may not be fully established.

Starting with the Fornell-Larcker criterion presented in Table 3, all AVE values (shown on the diagonal) exceed the squared correlations, further supporting strong discriminant validity.

Table 3: Fornell-Larcker Criterion

	Tax regulations	Licensing requirements	Employment and labor laws	Safety regulations	Enterprise Growth
Tax regulations	**0.754**				
Licensing requirements	0.472	**0.716**			
Employment and labor laws	0.453	0.381	**0.814**		
Safety regulations	0.432	0.375	0.697	**0.709**	
Enterprise Growth	0.265	0.345	0.334	0.334	**0.738**

(Source: Field Data, 2024)

Following the evaluation of the Fornell-Larcker Criterion, the Heterotrait-Monotrait Ratio (HTMT) was assessed as a key measure for determining discriminant validity in PLS-SEM. Recommended thresholds for HTMT help in establishing the distinctiveness of constructs, with a conservative threshold of 0.85 for conceptually distinct constructs and a more lenient threshold of 0.90 for those that are conceptually similar (Hair et al., 2021). The results presented in Table 4 show that all HTMT values are below 0.85, confirming that the discriminant validity of the variables has been effectively established (Rasoolimanesh, 2022).

Table 4: Heterotrait-Monotrait Ratio (HTMT)

	Tax regulations	Licensing requirements	Employment and labor laws	Safety regulations	Enterprise Growth
Tax regulations					
Licensing requirements	0.472				
Employment and labor laws	0.676	0.496			
Safety regulations	0.614	0.615	0.701		
Enterprise Growth	0.567	0.478	0.339	0.567	

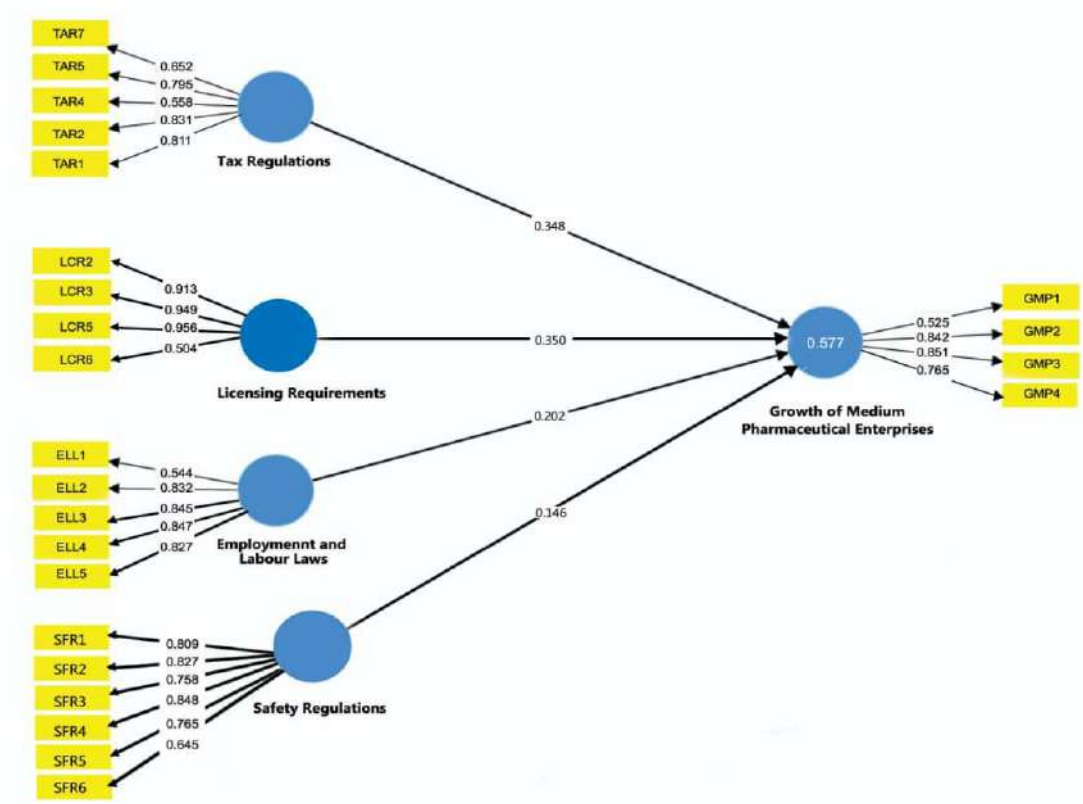
Source: Field data (2024)

Convergent Validity Analysis for the Measurement Model

After evaluating discriminant validity, the study proceeded to assess convergent validity within the measurement model. Convergent Validity Analysis in PLS-SEM is vital for determining how well a construct correlates with its indicators, ensuring that these indicators accurately reflect the underlying theoretical concept. This validity is primarily measured using the Average Variance Extracted (AVE), which represents the proportion of variance captured by a construct compared to the variance attributed to

measurement error. An AVE value of 0.50 or higher is deemed acceptable, indicating that the construct explains at least 50% of the variance in its indicators (Wang et al., 2023). The results presented in Table 2 reveal that all AVE values exceed 0.5, confirming the presence of convergent validity (Rasoolimanesh, 2022; Hair et al., 2021). This validation enhances the overall validity and reliability of the findings. Following the completion of all measurement model analysis tests, the accepted indicators are illustrated in Figure 2, along with their respective constructs.

Figure 2: Final Measurement Model



Structural Model Evaluation

After completing the Measurement Model Analysis, the study moved on to evaluate the structural model. Structural Model Evaluation in PLS-SEM involves several critical assessments to ensure the model's robustness and predictive capability, focusing on collinearity assessment, path coefficient evaluation, and effect size assessment (f^2). Together, these evaluations provide a comprehensive understanding of the structural model's performance and its ability to explain and predict relationships among constructs.

Structural Model Evaluation through Collinearity Statistics

Structural Model Evaluation through Collinearity Statistics is a crucial aspect of assessing the relationships among key factors in PLS-SEM. According to Hair et al. (2021), multicollinearity is indicated when the VIF exceeds 4.0, while a tolerance coefficient below 0.25 also suggests potential issues, as it is the reciprocal of the VIF. This study employed PLS-SEM to address concerns related to multicollinearity, and the results shown in Table 5 indicate that the variables did not exhibit multicollinearity, with VIF values ranging from 0.25 to 4.0. This range confirms that the predictor constructs are sufficiently distinct, ensuring the reliability of path coefficient estimates and enhancing the overall validity of the structural model.

Table 5: Variance Inflation Factor

Latent variable	Indicator	Outer VIF	Inner VIF
Tax regulations	TAR1	1.434	2.709
	TAR2	1.459	
	TAR4	1.389	
	TAR5	1.467	
	TAR7	1.455	
Licensing requirements	LCR2	1.855	1.684
	LCR3	1.818	
	LCR5	2.808	
	LCR6	2.906	
Employment and labor laws	ELL1	1.869	2.728
	ELL2	1.884	
	ELL3	1.967	
	ELL4	1.838	
	ELL5	1.878	
Safety regulations	SFR1	1.604	1.809
	SFR2	1.740	
	SFR3	1.678	
	SFR4	2.157	
	SFR5	2.195	
	SFR6	2.003	
Growth of medium enterprises	EG1	1.278	1.978
	EG2	1.267	
	EG3	1.289	
	EG4	1.245	

Source: Field data (2024)

Structural Model Evaluation through Path Co-efficient

Structural model evaluation through path coefficients in PLS-SEM is essential for assessing the strength and significance of relationships between constructs within a theoretical framework (Hair et al., 2021). Path coefficients indicate the direct effects of one latent variable on another, with their values representing both the magnitude and direction of these relationships. Typically, path coefficients need to exceed 0.1 to indicate a meaningful effect (Mohamed et al., 2018). The significance of these path coefficients is determined using the PLS bootstrapping method, which involves iterative random sampling with replacement from the original sample to generate t-values and p-values (Daoud, 2017; Fauzi, 2022). Smart PLS is the primary tool utilized in this process to assess the statistical significance of path coefficients. The results, including t-values and p-values, are presented in Table 7, allowing researchers to confirm or reject their hypotheses based on empirical evidence.

Structural Model Evaluation through the Coefficient of Determination

In this study, the explanatory power of the structural model is evaluated using R-squared and Adjusted R-squared values. R-squared represents the proportion of variance in the dependent variable explained by the independent variables, with values ranging from zero to one; an acceptable threshold for outcome variables is typically above 0.1 (Hair et al., 2021). For the growth of medium pharmaceutical enterprises, as demonstrated in Table 6, the R^2 is 0.577, and the adjusted R^2 is 0.559. These values indicate that the independent variables, including licensing requirements, tax regulations, employment and labor laws, and safety regulations, collectively explain approximately 57.7% of the variance in the growth of medium pharmaceutical enterprises. The remaining 42.3% is attributed to factors outside the scope of this study. The adjusted R^2, which is slightly lower at 55.9%, takes into account the number of predictors in the model, reinforcing its robustness and the significant influence of regulatory factors on enterprise growth. This level of explanatory power indicates a moderate effect size, considered acceptable in social science research (Daoud, 2017; Fauzi, 2022), emphasizing the critical role of regulatory compliance in fostering sustainable growth within the pharmaceutical sector.

Table 6: Coefficient of Determination (R^2)

	R-square	R-square adjusted
Enterprise Growth (EG)	0.577	0.559

Source: Field data (2024)

The f^2 Effect Size Assessment

In this study, the f^2 effect size assessment within SEM evaluates the impact of each predictor construct, licensing requirements, tax regulations, employment and labor laws, and safety regulations on the growth of medium-sized pharmaceutical enterprises. This measure helps determine the relative importance of each predictor in explaining the variance within the dependent variable, in accordance with the guidelines provided by Rasoolimanesh (2022). Effect sizes are classified as small (≥ 0.02), medium (≥ 0.15), or large (≥ 0.35) to indicate the significance of each predictor's contribution to the model's explanatory power (Jani & Mwakyusa, 2021). In this analysis (Table 7), all predictor variables achieved f^2 scores above the 0.02 threshold, confirming their meaningful contributions to the model, as recommended by Daoud (2017) and Fauzi (2022).

Specifically, Licensing requirements have a medium to large effect (f2 = 0.302) on growth, and the hypothesis of an effect was statistically supported (P<0.05). Tax regulations have a medium effect (f2 = 0.154) on growth, and the hypothesis was statistically supported (P<0.05). Employment and labor laws have a medium effect (f2 = 0.248) on growth, and the hypothesis was statistically supported (P<0.05). Safety regulations have a medium effect (f2 = 0.156) on growth, but the hypothesis was not statistically supported (P>0.05), suggesting the effect, while practically significant, may not be reliably consistent or requires further investigation. This assessment highlights the importance of individual predictors while refining the model by identifying the most impactful constructs, thereby enhancing the understanding of the relationships within the structural model.

Direct relationship hypothesis testing

Table 7 provides a summary of the structural model, examining the relationships between various regulatory factors and the growth of medium-sized pharmaceutical enterprises. Licensing requirements exhibit a path coefficient of 0.350, showing a strong positive influence on growth with a moderate effect size (f^2 = 0.302), a significant t-value of 3.768, and a p-value of 0.017, supporting the hypothesis. Tax regulations also positively impact growth, reflected in a path coefficient of 0.348 with a smaller effect size (f^2 = 0.154), a highly significant t-value of 1.809, and a p-value of 0.000, indicating support for the hypothesis. However, despite a t-value of 1.809 which is slightly below the acceptable threshold of 1.96 for a 95% confidence level indicates a strong relationship; the t-value of 1.809 could be due to a sample size. Even though the sample of 108 employed meets the minimum requirements for the PLS-SEM that ranges from 100 and above, a small sample reduces the power of the t-value (Memon et al., 2020). Employment and labor laws further contribute to growth with a path coefficient of 0.146, a medium effect size (f^2 = 0.248), and a t-value of 2.392 with a p-value of 0.001, confirming hypothesis support. Conversely, Safety regulations negatively influence growth, indicated by a path coefficient of -0.202. Despite a medium effect size (f^2 = 0.156) and a t-value of 3.324, the p-value of 0.071 is above the significance threshold, resulting in the hypothesis being unsupported. These results generally, indicate that growth of the medium pharmaceuticals firms in Tanzania are influenced .by favourable licensing, tax, and labour regulations; while safety regulations do not have a statically significant effect.

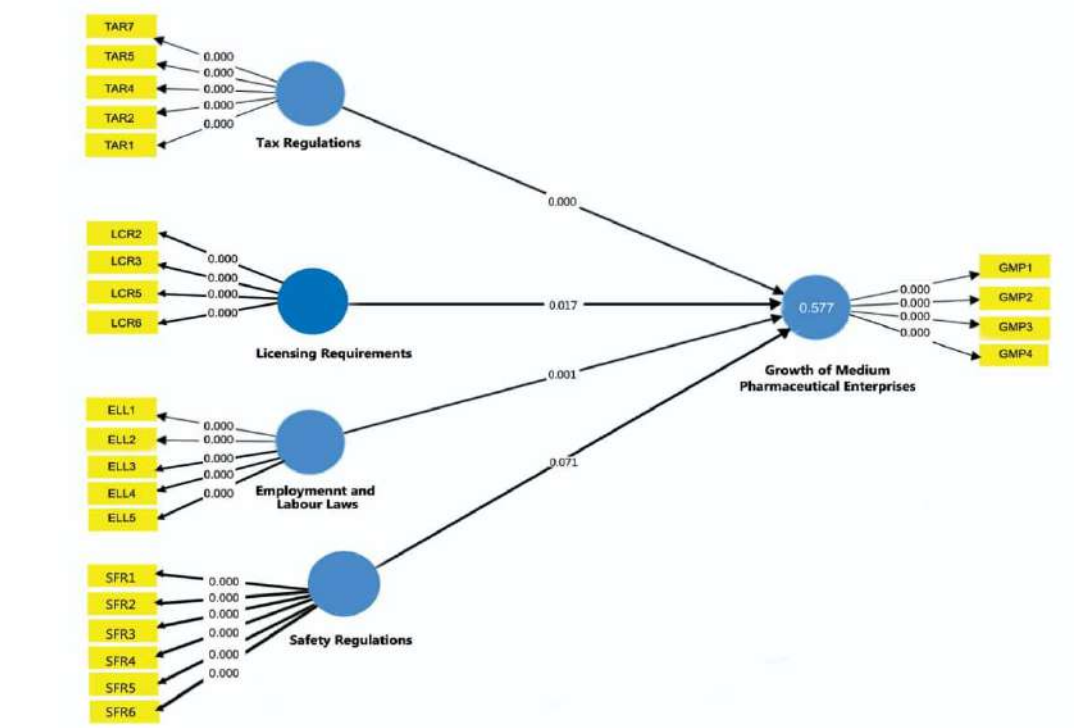
Table 7: Summary of Structural Model

Hypotheses paths	**Path coefficients**	**F^2**	**t-values**	**P values**	**Hypothesis status**
Licensing requirements -> Enterprise Growth	0.350	0.302	3.768	0.017	Supported
Tax regulations -> Enterprise Growth	0.348	0.154	1.809	0.000	Supported
Employment and labor laws -> Enterprise Growth s	0.146	0.248	2.392	0.001	Supported
Safety regulations -> Enterprise Growth	-0.202	0.156	3.324	0.071	Not Supported

Source: Field data (2024), attained using SmartPLS4

Figure3 presents the model assessment following the structural model evaluation tests, showcasing the variables and their corresponding p-values, as detailed in Table 7. The figure includes p-values for each indicator, all of which are considered acceptable since they fall below the 0.05 threshold.

Figure 3: Model Assessment



Model Fit Summary

Table 8 summarizes the model fit indices, presenting both the saturated and estimated models. The Standardized Root Mean Square Residual (SRMR) value for both models is 0.138, which is above the common threshold of 0.08. On average, these results exibit that residuals between observed correlations and model-implied correlations are about 13.8%, which is quite high. Then, these results indicate that there is room for improvement in the model by increasing variables or sample size. The discrepancy measures, dULS_ULS and d_G_d_G, are both reported at 5.286 and 1.468, respectively, and are identical for both models, suggesting consistent fit statistics. The Chi-square value of 863.923 also reflects model fit but should be interpreted with caution due to its sensitivity to sample size. Lastly, the Normed Fit Index (NFI) is 0.608, which falls below the recommended minimum of 0.90, indicating that the model could benefit from further refinement to enhance fit (Hair et al., 2021).

Table 8: Model Fit Summary

	Saturated model	Estimated model
SRMR	0.138	0.138
d_ULS	5.286	5.286
d_G	1.468	1.468
Chi-square	863.923	863.923
NFI	0.608	0.608

Source: Field data (2024), attained using SmartPLS4

Discussion

First hypothesis was hypothesized that Tax regulations positively influence the growth of medium pharmaceutical enterprises in Tanzania. In hypothesis test results (Table 7), this association was also positively significant. This support for the hypothesis suggests that effective tax regulation management fosters a stable environment for business growth, building stakeholder trust and encouraging investment. The positive impact of tax regulations can be attributed to a more predictable financial environment, which helps businesses plan their expenses and investments effectively. Adherence to tax regulations reduces the risk of legal penalties, allowing businesses to maintain operational continuity. Additionally, by maintaining good tax practices, enterprises can gain access to governmental programs and financial support, which may foster further growth. This stability in tax obligations allows firms to allocate resources confidently toward expansion and innovation.

The findings of the present study align with those of Sinha and Kesselheim (2022) and Pezzola and Sweet

(2022) in demonstrating the significant impact of tax regulations on the growth of pharmaceutical enterprises. In those studies, it showed how tax regulations and supportive policies promoted profitability and reinvestment in innovation for U.S. pharmaceutical companies. These similarities imply that despite geographic and contextual differences; the regulatory environment significantly shapes growth dynamics in pharmaceutical industries worldwide. Pezzola and Sweet (2022) also illustrating the crucial role of regulatory frameworks in shaping pharmaceutical markets, particularly in developing countries. These similarities highlight the importance of tailored tax regulatory approaches in fostering industry growth and addressing local market needs, suggesting that effective tax regulatory frameworks are essential for enhancing the performance of pharmaceutical enterprises in emerging economies.

Second hypothesis was hypothesized that licensing requirements positively influence the growth of medium pharmaceutical enterprises. In hypothesis test results (Table 7), the association between these variables was positively significant. This indicates that adhering to licensing regulations likely promotes stable growth, allowing enterprises to operate without regulatory disruptions. This positive influence may be attributed to several factors. First, compliance with licensing requirements provides legitimacy to enterprises, increasing consumer confidence and building trust with regulatory bodies, which is crucial in the pharmaceutical industry. Furthermore, licensed enterprises often have access to industry networks and government incentives that encourage business growth. Additionally, meeting licensing requirements ensures that enterprises adhere to quality standards, reducing risks associated with non-compliance and fostering long-term stability.

The findings of the present study align with those of Sinha and Kesselheim (2022), demonstrating a significant influence of licensing requirements, on the growth of medium-sized pharmaceutical enterprises. Similar to Sinha and Kesselheim's study, which found that regulatory compliance, affects market entry and growth dynamics in the U.S. pharmaceutical sector. These similarities suggest that licensing requirements play a crucial role in shaping business growth trajectories across diverse contexts. Likewise, the findings of the present study also resonate with the work of Ndomondo-Sigonda et al. (2021), Charles (2014) and Ministry of Industry, Trade and Investment (2018) which emphasized the significance of harmonized regulatory frameworks including licensing requirements in enhancing regulatory capacity within the East African Community. Both studies acknowledge the importance of effective regulatory structures in promoting growth and public health outcomes. The present study highlights how specific regulatory factors, such as licensing requirements, directly influence the growth of medium-sized pharmaceutical enterprises in Tanzania, extending the findings of Ndomondo-Sigonda et al. (2021) and Charles (2014) by focusing on the operational impact of regulatory compliance on business growth.

Third hypothesis was hypothesized that Employment and Labor Laws positively influence the growth of medium pharmaceutical enterprises. In hypothesis test results (Table 7), the association between these variables was positively significant. This finding implies that alignment with labor laws helps these enterprises build a stable workforce, thereby supporting growth. The growth attributed to employment and labor laws is likely due to the stability and productivity that come from fair labor practices. When employees' rights are safeguarded, job satisfaction and morale improve, resulting in higher productivity and lower turnover rates. Moreover, compliance with labor laws enhances the company's reputation as a fair employer, attracting skilled talent and fostering a committed workforce that drives business growth. Also, fair wages and benefits align with regulatory requirements and contribute to a stable internal environment conducive to growth.

The findings of the present study align with those of Sinha and Kesselheim (2022) in demonstrating the significant impact of regulatory frameworks including employment and labor laws on the growth of pharmaceutical enterprises. Both studies highlight how specific regulatory factors, such as employment and labour laws, positively influence business growth. The present study indicates that regulatory structures, particularly in terms of employment and labour laws, significantly contribute to the growth of medium-sized pharmaceutical enterprises in Tanzania. Again, the present study shares similarities with Mallett et al. (2022) in highlighting the influence of employment and labor law regulations on the growth of SMEs. Both studies emphasize the dual role of regulations in either hindering or fostering business growth. The present study resonates with these findings, particularly in showcasing how compliance and labor laws affect the growth of medium-sized pharmaceutical enterprises in Tanzania. These connections imply that regulatory frameworks including employment and labor law, when effectively structured, can significantly enhance industry performance, suggesting a universal relevance of tailored regulations for fostering growth in diverse market contexts.

Fourth hypothesis was hypothesized that Safety regulations positively influence the growth of medium-sized pharmaceutical enterprises. In the hypothesis test results (Table 7), however, this association was not significant. The unsupported hypothesis suggests that while safety regulations are essential for compliance, they may introduce additional costs or operational challenges that could hinder growth if not well-managed. While safety regulations ensure a secure working environment and can help prevent costly accidents, the associated expenses may hinder immediate growth. Compliance with stringent safety

protocols often requires investments in safety training, equipment, and procedures, which can strain financial resources, especially for medium-sized enterprises with limited budgets. Additionally, safety compliance can lead to operational delays, potentially impacting productivity and growth. Therefore, while essential for employee well-being, the cost and operational demands of safety regulations may challenge growth if not well-balanced with business needs.

The findings of the present study reveal a divergence from Sharma's (2019) research, which highlighted the critical role of regulatory compliance in enhancing product quality and public health outcomes in India's pharmaceutical sector. Similarly, the present study also contrasts with the findings of Ndomondo-Sigonda et al. (2021), which underscored the importance of regulatory capacity and harmonization in enhancing the effectiveness of medicines regulatory agencies in the East African Community. Their study indicated that inadequate regulatory capacity including safety regulations leads to the circulation of substandard medical products, emphasizing the necessity of policy and legal frameworks for effective regulation. However, the present study's hypothesis regarding the influence of safety regulations on growth yielded insignificant results, suggesting that safety regulations may not significantly contribute to the growth of medium-sized pharmaceutical enterprises in Tanzania. This discrepancy highlights differences in geographic focus and regulatory contexts, as Ndomondo-Sigonda et al. (2021) concentrated on harmonization efforts across multiple East African countries while the current research focused specifically on Tanzania's regulatory environment.

Conclusions

The study examined the effect of the regulatory frameworks on the growth of medium-sized pharmaceutical enterprises in Tanzania. The results show that tax regulations, licensing requirements, and employment and labour laws positively and significantly influence the growth of medium-sized pharmaceutical enterprises in Tanzania. The findings are in line with Institutional Theory, which posits that compliance with regulatory norms provides stability and legitimacy for businesses, which results to promote organizational stability and growth. These findings align with prior studies, such as those by Sinha and Kesselheim (2022) and Pezzola and Sweet (2022), Ndomondo-Sigonda et al. (2021), Sinha and Kesselheim (2022), which demonstrated similar outcomes in different regions, indicating the universal role of regulatory frameworks in fostering enterprise growth. Conversely, safety regulations had no effect to the growth of medium-sized pharmaceutical enterprises in Tanzania. Although important these results pause an argent question why is safety not a reason for growth in enterprises? Possibly the compliance costs are too high or is not a matter of concern for business owners as manpower can easily be substituted. This finding contrasts with the predictions of Institutional Theory and prior research, such as that of Sharma (2019) and Ndomondo-Sigonda et al. (2021), which highlighted the positive effect of safety requirements as compliance on industry performance.

Implications

The study contributes to the institutional theory with the positive and significant results. This explains that organizations operate within broader legal and social systems which they operate and must conform to these external requirements and gain legitimacy and access critical resources External pressure here described as tax regulations, licensing requirements, and employment and labour laws significantly contribute to enterprise growth by promoting operational alignment and institutional legitimacy. These regulatory elements help firms establish credibility, reduce legal risks, and access vital resources, ultimately supporting their development within a formalized and structured business environment. Practically the study results highlight the importance of proactive regulatory compliance to foster business growth. Managers can prioritise adherence to tax regulations and licensing requirements, as these have been shown to create a stable operational environment and enhance the enterprise's legitimacy in the market. This would allow managers to allocate resources more effectively across other compliance areas that drive growth, creating a holistic approach to regulatory management that supports both compliance and business objectives. Managers of pharmaceutical enterprises can leverage these findings by investing in compliance capabilities. Since tax, licensing, and labor compliance were linked to growth, firms should strengthen their internal processes for meeting these regulations efficiently. By turning regulatory compliance into an organizational strength, enterprises might gain a competitive edge. In addition, the study results draw implications to the policymakers for them they can support existence of clear guidelines and accessible resources; facilitate compliance also facilitate means to simplify tax compliance procedures as well as consider streamlining certain regulatory processes as a trial/pilot initiative.

Limitations and Future Research

This study examined the effects of regulatory frameworks on the growth of medium-sized pharmaceutical enterprises in Tanzania by employing a cross-sectional survey design, which only captures data at a single point in time. This snapshot might overlook trends and fluctuations in regulatory impacts over time, especially given the dynamic nature of Tanzania's regulatory environment. A further limitation of this study is its focus solely on medium-sized pharmaceutical enterprises within the urban region of Dar es Salaam. As a result, a smple size of 108 employed in this study has led to a problem in model fit and

small t-value of 1.809 for a tax construct, which is below a threshold of t-value of 1.96. This specificity may have limited the number of sample size as well as the generalizability of the findings to smaller or larger enterprises and to those operating in rural areas, where regulatory challenges, resource availability, and market dynamics could differ significantly. Urban enterprises may have better access to resources and regulatory support, while rural counterparts might face distinct obstacles, such as infrastructure limitations and varying degrees of regulatory enforcement. Future research may consider a longitudinal approach, tracking firms over time to establish causal effects of regulatory changes on growth. A mixed-methods design could also provide depth, for instance, qualitative interviews with TMDA officials or enterprise managers to understand the tricks behind compliance challenges. Finally, examining moderating factors such as a firm's access to finance or managerial capacity could reveal why some medium enterprises thrive under regulation while others struggle, extending the insights of this study.

References

Agu, E. E., Efunniyi, C. P., Abhulimen, A. O., Obiki-Osafiele, A. N., Olajide, S. O., & Ibrahim, A. A. (2023). Regulatory frameworks and financial stability in Africa: A comparative review of banking and insurance sectors. *Finance & Accounting Research Journal, 5*(12), 444–459.

Akang, A. U. (2024). Regulatory Compliance and Access To Finance: Implications for Business Growth in Developing Economies. *Sciental Journal of Education Humanities and Social Sciences*, *1*(2), 8–23.

Aksom, H. & Tymchenko, I. (2020). How institutional theories explain and fail to explain organizations. *Journal of Organizational Change Management, 33*(7), 1223–1252. https://doi.org/10.1108/JOCM-05-2019-0130

Besigomwe, K. (2024). Administrative Law and the Regulation of Informal Sector Enterprises in Uganda. *Cognizance Journal of Multidisciplinary Studies, 4*, 532-543.

Castillo, A., Rescalvo-Martin, E. & Karatepe, O.M. (2026). How is common method bias addressed using partial least squares structural equation modeling in hospitality and tourism research? *Tourism Review, 81*(1), 204–228. https://doi.org/10.1108/TR-07-2025-0762

Charles, G. (2014). The effect of the regulatory framework on the competitiveness of the dairy sector in Tanzania. *International Journal of Public Sector Management 27*(4), 296-305. https://doi.org/10.1108/IJPSM-08-2011-0100

Chukwudi, C. G., Augustus-Daddie, J., & Achiole, E. A. (2015). The Impact of Regulatory Environment on the Effectiveness of Small and Medium Scale Enterprises: A Study of Selected Small and Medium Scale Enterprise in Owerri. *Journal of Investment and Management, 4*(6), 311-318. 10.11648/j.jim.20150406.14

Cohen, L., Manion, L., & Morrison, K. (2018). Research Methods in Education (8th ed). London: Routledge.

Daoud, J. (2017). Multicollinearity and Regression Analysis. *Journal of Physics: Conference Series, 949*(1), 1-6. DOI: 10.1088/1742-6596/949/1/012009

Divanbeigi, R., & Ramalho, R. (2022). Business regulations and growth. World Bank Policy Research Working Paper, (7299). Washington DC.

DiMaggio, P. J., & Powell, W. W. (1983). The iron cage revisited: Institutional isomorphism and collective rationality in organizational fields. *American Sociological Review, 48*(2), 147–160.

Fauzi, M. A. (2022). Partial least square structural equation modelling (PLSSEM) in knowledge management studies: Knowledge sharing in virtual communities. *Knowledge Management and E-Learning, 14*(1), 103–124.

Fimbo, A. M., Sillo, H. B., Nkayamba, A., Kisoma, S., Mwalwisi, Y. H., Idris, R., Asiimwe, S., Githendu, P., Ogbuoji, O., Morrison, L., Bump, J. B., & Kaale, E. (2024). Strengthening regulation for medical products in Tanzania: An assessment of regulatory capacity development, 1978–2020. *PLOS Global Public Health, 4*(10), 1–29.

Francisco, J. P., Flaminiano, J. P., Abad, J. U., & Santamaria, J. G. (2023). Do Regulatory Compliance Costs Hinder Growth among Small and Medium Enterprises in the Philippines? *SSRN Electronic Journal*, *11*(4), 1–27.

Goel, N., Kota, H. B., Singh, G., Mir, M., & Kumar, B. (2020). *Technological Innovation and Regulation as Determinants of Business Growth: An Institutional FDI Fitness Theoretical Framework*. In Technological Innovations for Sustainability and Business Growth (pp. 39-55). IGI Global.

Gostin, L. O., Wood, A. J., & Cuff, P. A. (2020). Regulating medicines in a globalized world with increased recognition and reliance among regulators: a national academies report. *JAMA, 324*(2), 145-146.

Hair, J. F., Hult, G. T. M., Ringle, C. M., Sarstedt, M., Danks, N. P., & Ray, S. (2021). *Partial Least Squares Structural Equation Modeling (PLS-SEM) using R*. In Classroom Companion: Business.

Jani, D., & Mwakyusa, J. R. P. (2021). Residents' perception of festival impacts and satisfaction: a focus on Zanzibar international film festival (ZIFF). *International Journal of Event and Festival Management, 12*(4), 365–379.

Köhler, C., & Hartig, J. (2019). Reliability and Validity. International Encyclopedia of Human Geography, *Second Edition, 7*(4), 393–396.

Macha, J., & Mtei, G. (2022). Assessing the impact of health sector reforms in Tanzania: A public

expenditure review approach. *BMC Health Services Research, 15*(1), 222-229.
Mallett, O., Wapshott, R., & Vorley, T. (2022). The impact of regulation on small business growth: Evidence from the UK. *Journal of Small Business and Enterprise Development, 29*(3), 421–438.
Matsuda, Y. (2019). Global regulatory landscape. *Aaps Pharmscitech, 20*, 1-4.
Memon, M.A., Ting, H., Cheah, J., Thurasamy, R., Francis Chuah, F. & Cham, T.H. (2020). Sample Size for Survey Research: Review and Recommendations. Journal of Applied Structural Equation Modeling, 4(2), i-xx. https://doi.org/10.47263/JASEM.4 (2)01
Meyer, J. W., & Rowan, B. (1977). Institutionalized organizations: Formal structure as myth and ceremony. *American Journal of Sociology, 83*(2), 340–363.
Miles, H., & Huberman, A. M. & Saldana (2014). *Qualitative data analysis a methods sourcebook*, 3.
Ministry of Industry, Trade and Investment (2018). Blueprint for Regulatory Reforms to Improve the Business Environment. https://www.brela.go.tz/uploads/documents/sw-1631096805-Blue%20print.pdf
Ministry of Health & Ministry of Industrialization, Trade and Enterprise Development. (2020). Kenya pharmaceutical industry: Diagnostic report 2020 – Summary. Nairobi: Republic of Kenya. https://www.health.go.ke
Mohamed, Z., Ubaidullah, N. & Yusof, H.I. (2018). An Evaluation of Structural Model for Independent Learning Through Connectivism Theory and Web 2.0 Towards Students' Achievement. *International Conference on Applied Science and Engineering, 175*, 1-5.
Ndomondo-Sigonda, M. M., Naidoo, S., Masota, N. E., Ng'andu, B., & Kaale, E. (2021). Harmonization of medical products regulation: a key factor for improving regulatory capacity in the East African Community. *BMC Public Health, 21*, 1-13.
Ndomondo-Sigonda, M., Miot, J., Naidoo, S., Ambali, A., & Ngum, N. A. (2021). The African Medicines Regulatory Harmonization initiative: Progress to date. BMC Public Health, 21(1), 1–10. https://doi.org/10.1186/s12889-021-10169-1
Ngum, N. A., Otineo, P., Mwatondo, A., Njogu, J. G., & Taylor, A. (2025). Suggested improvements to the EAC-MRH joint review process. Centre for Innovation in Regulatory Science (CIRS). https://cirsci.org
Nwoke, A. C. (2024). Regulatory compliance and risk management in pharmaceuticals and healthcare. *International Journal of Regulatory Affairs, 12*(2), 45–53.
Oliver, C. (1991). Strategic responses to institutional processes. Academy of Management Review, 16(1), 145–179.
Pazi, R. M. (2020). The Legal Framework Limitations for the Effective Intergovernmental Relations in Tanzania. *J. Public Adm. Gov*, *8*, 246-255.
Peck, F., Jackson, K., & Mulvey, G. (2015). Regulations: friend or foe? Regulation and growth-oriented small businesses. In: Institute of Small Business and Entrepreneurship (ISBE) Conference, 11-12 November 2015, Glasgow, Scotland. (Unpublished)
Peck, F., Mulvey, G. & Jackson, K. (2018). Regulation and growth-oriented small businesses in North-West England. Journal of Small Business and Enterprise Development, 25(3). https://doi.org/10.1108/JSBED-07-2017-0232
Pezzola, A., & Sweet, C. M. (2022). Global pharmaceutical regulation: the challenge of integration for developing states. *Globalization and health*, *12*, 1-18.
Rasoolimanesh, S. M. (2022). Discriminant validity assessment in PLS-SEM: A comprehensive composite-based approach. *Data Analysis Perspectives Journal, 3*(2), 1–8.
Rutta, E., Liana, J., Embrey, M., Johnson, K., Kimatta, S., Valimba, R., & Sillo, H. (2021). Accrediting retail drug shops to strengthen Tanzania's public health system: an ADDO case study. *Journal of pharmaceutical policy and practice*, *8*, 1-15.
Sangeda, R. Z., Ndabatinya, C. J., Maganga, M. B., Nkiligi, E. A., Mwalwisi, Y. H., & Fimbo, A. M. (2024). Good manufacturing practice inspections conducted by Tanzania medicines and medical devices authority: a comparative study of two fiscal years from 2018 to 2020. *Journal of Pharmaceutical Policy and Practice, 17*(1). https://doi.org/10.1080/20523211.2024.2399722
Scott, W. R. (2008). Institutions and organizations: Ideas and interests (3rd ed.). Sage Publications.
Sharma, A., Gamta, V., & Luthra, G. (2023). Regulatory Compliance in the United States: A Comprehensive Analysis of USFDA Guidelines and Implementation Strategies. *Journal of Pharmaceutical Research International, 35*(17), 41–50.
Sharma, D. (2019). Regulatory affairs in the pharmaceutical industry: A qualitative examination. *Journal of Pharmaceutical Policy and Practice, 12*(1), 1–7.
Sinha, R., & Kesselheim, A. S. (2022). Tax policies and regulatory impacts on pharmaceutical enterprise growth in the United States. *Health Affairs, 41*(4), 572–580.
Sjögrén, H. & Syrjä, P. (2015). Regulation compliance in small Finnish companies. International Journal of Law and Management, 57(6):649-661. DOI: 10.1108/IJLMA-03-2015-0010
Sosthenes, J., Kitindi, E.G., & King'ori, J. L. (2022). The Internal Audit Functions: Competence, Effectiveness and External Auditors' Reliance in Tanzania. *Business Management Review, 25*(2), 77-94.
TMDA. (2021). The United Republic of Tanzania, Tanzania Medicines and Medical Devices Act Cap 219.
TMDA (2024). Tanzania Medicines and Medical Services Authority registry. https://www.tmda.go.tz/

Udo, A. (2024). Policy Adherence and Business Growth: Exploring The Relationship In Small And Medium Enterprises. *Zien Journal of Social Sciences and Humanities*, *7*, 1–12.

Um, S. I., Sohn, U. D., Jung, S. Y., You, S. H., Kim, C., Lee, S., & Lee, H. (2022). Longitudinal study of the impact of three major regulations on the Korean pharmaceutical industry in the last 30 years. *Health Research Policy and Systems*, *20*, 1-12.

Um, S., Kim, D., & Lee, Y. (2023). Regulatory reform and innovation in the Korean pharmaceutical industry: A longitudinal analysis. *International Journal of Health Policy and Management, 12*(3), 212–220.

United Republic of Tanzania, Small and Medium Enterprise Development Policy 2002.

Wang, X., French, B. F., & Clay, P. F. (2023). Convergent and discriminant validity with formative measurement: A mediator perspective. *Journal of Modern Applied Statistical Methods, 14*(1), 83–106.

Zait, A., & Bertea, P. E. (2021). Methods for testing discriminant validity. *Management & Marketing, 9*(2), 217–224.

Zhang, T. (2025). The effects of regulation on innovation in the medical device industry. [Master's thesis, Eindhoven University of Technology]. https://pure.tue.nl