RESEARCH PAPER

Beyond Regulation: Institutional Effectiveness, Governance Maturity, and Sustainability Outcomes in the Pharmaceutical Sector

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Abstract

This study examines sustainability implementation in the pharmaceutical sector through an institutional effectiveness perspective, emphasizing the role of enforcement consistency, governance maturity, financial constraints, and stakeholder engagement. The mixed-method approach was used with primary data of 100 pharmaceutical professionals, which included the combination of quantitative analysis and qualitative insights. The results show that consistency in enforcement greatly reinforces the correlation between regulatory stringency and sustainability outcomes, and transparency positively impacts sustainability both directly and indirectly by involving stakeholders. Policy incentives have a positive relationship with the sustainability outcomes, whereas financial constraints are structural constraints to adoption. Governance maturity is also identified to be a good predictor of sustainability performance with the importance of institutionalized compliance systems and reporting procedures. A second major implication of the research is that regulation can be more effective through technology-based monitoring (e.g., digital compliance systems and data-driven sustainability reporting). This research can be valuable to policymakers and other stakeholders in the pharmaceutical industry who would like to enhance sustainable pharmaceutical practices by laying the focus on institutional effectiveness and not on the regulatory design.

Keywords: *Sustainable Pharmaceutical Regulation, Institutional Effectiveness, Enforcement Consistency, Governance Maturity, Stakeholder Engagement*

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1. Introduction

The pharmaceutical sector is in the middle of a radical change where sustainability is taking center stage in the regulatory and operating models (Saxena et al., 2022). In the past, drug safety, quality assurance, and regulatory compliance were the main concerns of pharmaceutical companies, but growing demands on the sector, environmental issues, and demands on long-term economic efficiency have necessitated the industry to incorporate environmental stewardship, social responsibility, and long-term economic

efficiency into its operations (Bade et al., 2024). The specifics of pharmaceutical production, namely the active use of resources, the creation of dangerous wastes, and the high compliance level, make the sustainability adoption urgent and difficult. To overcome these obstacles, the regulatory laws have increasingly adopted sustainability-based provisions such as environmental standards, compulsory reporting, incentive schemes, and risk reduction requirements in the quest to ensure the adoption of responsible production measures (El-Hakim & AbouZeid, 2024). With these changes, an ongoing issue lies in the difference between regulatory framework purpose and their application at organizational levels. The very existence of regulatory mechanisms is not enough to ensure sustainable results; instead, the success of the regulatory mechanisms relies on institutional and organizational determinants, which shape the way firms perceive, react to, and implement the regulatory requirements. The alignment of firms to their strategic goals, governance forms within the firm, and operational ability to track compliance through technology-based instruments are key determinants of a successful implementation of sustainability (Solaimani, 2024).

According to recent research findings, policy incentives as well as transparency are quite crucial, but the effectiveness of these incentives depends on organizational and environmental circumstances. Stability of enforcement, governance maturity, financial feasibility, and use of technology-enhanced monitoring tools are emerging as critical yet less studied aspects (Huang et al., 2023). Tough yet loosely enforced rules may not generate sufficient compliance pressure, and smaller financial-base companies may not be in a position to adopt sustainability practices, despite the policy incentives that are being offered (Delmas & Toffel, 2008). Likewise, lack of well-organized governance frameworks, formal reporting, and online monitoring systems may interfere with successful implementation of sustainability in organizational procedures and decision-making. This paper fills these gaps by taking an institutional effectiveness approach to the analysis of mechanisms that drive sustainability results in the pharmaceutical industry (Pasape & Godson, 2022). In particular, it explores: (i) how enforcement consistency moderates the effectiveness of regulatory stringency, (ii) how stakeholder engagement mediates the transfer of transparency to tangible sustainability results, (iii) the limiting effect of financial constraints on policy implementation, and (iv) the direct effect of the maturity of governance on sustainable practices. The synthesis of these constructs to produce a complete analytical framework enables the study to present a complex understanding of how regulatory design, which controls the organization, and technology-based monitoring, all affect the sustainability performance (Hariyani et al., 2025).

The findings would probably facilitate significant information for both policymakers and regulators and industry players. To illustrate, the article reveals that compliance and monitoring systems can be supported by technology and assist in enhancing the enforcement consistency, stakeholder involvement, and the more transparent reporting that will result in the more efficient sustainability practices (Stanley Chidozie Umeorah et al., 2024). By doing so, the study not only adds to the existing theory on institutional effectiveness but also offers practical solutions to interventions on transformative sustainability in pharmaceutical operations, which will be in line with global standards and enhance sectoral resilience (Golzarjannat & Gustafsson, 2025).

1. How does enforcement consistency influence the effectiveness of regulatory stringency in improving sustainability outcomes in the pharmaceutical industry?
2. Does transparency enhance stakeholder engagement, thereby strengthening sustainability implementation in pharmaceutical firms?
3. To what extent do financial constraints weaken the impact of policy incentives on sustainability outcomes?
4. How does governance maturity influence the alignment between regulatory frameworks and sustainable pharmaceutical practices?

Research Objectives

1. To examine the moderating role of enforcement consistency in the relationship

between regulatory stringency and sustainability outcomes.
2. To evaluate the mediating role of stakeholder engagement in the relationship between regulatory transparency and sustainability outcomes.
3. To analyze the moderating effect of financial constraints on the relationship between policy incentives and sustainability performance.
4. To assess the influence of governance maturity on sustainable pharmaceutical practices and outcomes.

2. Literature Review

The concept of sustainability of the pharmaceutical industry has gained significance with the growing importance of environmental issues, environmental laws, and expectations of stakeholders. Pharmaceutical manufacturing processes are very complex, energy-intensive, and hazardous in terms of waste generation, hence the necessity to incorporate sustainability (Muthoni L., 2025). The regulatory institutions and international bodies have expanded their frames to include environmental compliance, social responsibility, and economic efficiency. Nonetheless, the quality of such regulatory mechanisms tends to differ among firms because of the difference in the quality of enforcement, governance, financial capabilities, and technological capabilities. Though the existing literature is keen on the relevance of regulatory frameworks, it is biased in that it does not consider the institutional context that determines the effectiveness of the regulatory frameworks in providing actual sustainability outcomes (Kadhim et al., 2025).

2.1 Sustainable Regulation in the Pharmaceutical Sector

One of the most regulated industries is the pharmaceutical market, which directly impacts the health of the population, the safety of the products, and the levels of quality (Tabersky et al., 2018). The old regulatory frameworks were focused on efficacy and safety, but the new frameworks included the aspects of sustainability such as green chemistry, emissions control, waste reduction, and resource efficiency. The concept of sustainable pharmaceutical development is now considered to be multidimensional, combining the performance based on environmental, social, and economic aspects. Jairoun et al. (2025) note that the eco-friendly pharmaceutical production regulatory interventions may drastically decrease the environmental risk, whereas van Vliet et al. (2025) underline the significance of structured frameworks of the greener pharmaceutical lifecycle management (Jairoun et al., 2025).

Despite these developments, the sustenance results are not assured by the mere existence of regulations. These companies are likely to possess a token or token conformity, particularly in cases where the venues of their enforcement are feeble or even in those cases where sustainability is not an element or component of the strategic planning. The variation in the size of the firm, technological capability, and exposure to the global market also leads to the differences in sustainability performance. Further, the existing literature addresses the design of regulations more but not the effectiveness of implementation, resulting in partial knowledge of the operation of sustainability policies in reality (Iraldo et al., 2011). This shows that there is a necessity to move the focus towards regulatory existence to regulatory effectiveness.

2.2 Enforcement Consistency and Institutional Effectiveness

One of the aspects that lead to the effectiveness of a regulatory system is regulatory consistency. Even stringent rules may not work where there is inconsistent implementation that may be either weak or patchy in various organizations. Regulatory consistency increases the regulatory credibility and lowers skepticism and renders sustainability requirements solemn (Hariyani et al., 2025). In the institutional theory view, compliance is both reaction-based on the reaction to formal rules and promise-based on monitoring and enforcement that influence compliance behavior (Hariyani et al., 2025).

Asif et al. (2019) have discovered that environmental regulations are effective in the event of robust and consistent enforcement mechanisms because they decrease opportunistic behavior and result in real compliance. But the literature seems to consider

regulatory stringency as a one-sided determinant of sustainability but has not given enough attention to the quality contribution of enforcement. This creates an empirical gap, as the best way of regulation is one that is applied on a frequent basis. In such a way, uniformity in enforcement offers itself as a key institutional mechanism that improves the connection between regulatory rigor and sustainability performance by transforming regulatory anticipations into tangible organizational behavior (Asif, 2019).

2.3 Transparency, Stakeholder Engagement, and Sustainability

Transparency is an important governance instrument that enhances accountability, regulatory transparency, and compliance attitude. The transparency systems enhance the disclosure practices, and firms can be able to see the sustainability requirements (Sari & Muslim, 2024). In addition, transparency aids in stakeholder interaction since it promotes transparency and information disclosure. By the companies posting the information concerning sustainability, they will have more chances of engaging the stakeholders such as regulators, communities, investors, and suppliers.

The article by Suhartini et al. (2024) has demonstrated that sustainability reporting boosts stakeholder trust and the responsibility of an organization considerably. This exchange will increase the application of sustainability through promoting cooperation, increasing responsiveness, and encouraging adherence to sustainable practices. Nevertheless, in the existing literature, transparency and stakeholder engagement are frequently considered independently, being unable to fully reflect the mutually supportive nature of the two. It is also empirically inconsistent whether to believe that transparency has a direct positive impact on outcomes of sustainability or whether transparency has an indirect impact on outcomes of sustainability through stakeholder mechanisms. Thus, the idea of stakeholder engagement may be presented as a mediating variable between the effect of transparency on sustainability results, and the importance of participatory governance could be stressed (Suhartini et al., 2024).

2.4 Policy Incentives and Financial Constraints

Techniques of supporting innovations, tax incentives, and subsidies are widely used in order to promote sustainability in the pharmaceutical industry. These incentives allow for decreasing the financial cost of green technologies and sustainable production practices. The effectiveness of these incentives but highly relies on financial constraints faced by firms.

Fewer financial resources might mean that the companies with less financial means will struggle to apply sustainability initiatives even with the policy. According to the significant obstacle to sustainable investments' adoption is financial constraints due to initial costs, long payback periods, and uncertainty about returns. Even though policy incentives are aimed at encouraging adoption of sustainability, they are likely to have impacts on it based on the financial capacity of firms. This conditional relationship has not been adequately researched in the past, especially in the emerging economies where constraints of resources are more evident. Therefore, financial constraints are critical issues that may limit the extent of policy incentives to the real sustainability performances (Kumar & Verma, 2022).

2.5 Governance Maturity and Sustainable Pharmaceutical Practices

Governance maturity refers to the extent to which sustainability is embedded within organizational systems, policies, and decision-making processes. It includes ESG reporting, compliance structures, performance monitoring, and accountability mechanisms. Moussa et al. (2024) highlight that firms with higher governance maturity demonstrate better sustainability performance due to structured systems and strategic integration of ESG practices. Similarly, show that governance mechanisms significantly enhance sustainability reporting quality and organizational transparency (Moussa et al., 2024).

Governance maturity involves to what extent the issue of sustainability has been incorporated in the organizational systems, policies, and decision-making processes. It involves ESG reporting, compliance systems, performance monitoring, and accountability. also found that more established firms regarding governance have a better sustainability performance due to the systematized systems and strategic

internalization of ESG practices. Likewise, demonstrate that the quality of sustainability reporting and transparency in the organization is greatly promoted by governance mechanisms (Eccles et al., 2014).

A resource-based perspective (RBV) of governance maturity can be considered as a type of internal resource of an organization that provides a competitive advantage based on the capability to implement sustainability measures successfully (Madhani, 2009). Nevertheless, the current literature tends to consider governance as an enabling factor as opposed to a driving force of sustainability performance. This limits the meanings of the direct correlation between the governance maturity and sustainability performance. Hence, the concept of governance maturity must be considered as a pivotal factor in sustainable pharmaceutical practices, as opposed to a marginal one.

2.6 Research Gap

Whereas there has been existing literature on sustainability in the pharmaceutical industry, it is still in bits and has never been integrated into one perspective. The regulatory frameworks, policy incentives, or governance mechanisms are studied separately, but not in regard to their joint and interactive impact on sustainability outcomes (Bag-Out, 2016). Furthermore, not much research has been done on the consistency of the enforcement, financial issues, and governance maturity as interconnected variables that determine the sustainability implementation. Moreover, technology-enabled monitoring systems (digital compliance tools and ESG reporting platforms), which have been largely not considered by previous research, can also contribute to regulatory effectiveness. There are also some inconsistencies empirically on how effective transparency and policy incentives are, especially in resource-constrained settings (Kolk, 2016). Hence, a holistic framework that combines regulatory, organizational, and institutional variables to comprehend sustainability outcomes more is necessary. This paper fills this gap by exploring the role of consistency of enforcement, stakeholder involvement, financial limitations, and maturity of governance in shaping sustainable pharmaceutical practices in a more holistic and implementation-focused manner (Montiel & Delgado-Ceballos, 2014).

3. Conceptual Framework and Hypotheses Development

The present study approaches the research problem using an institutional effectiveness approach to examine how regulatory and organizational mechanisms are related to the sustainability outcomes in the pharmaceutical industry. The framework relies on the institutional theory that explains the impact of the external pressures on the organizational behavior in terms of regulatory stringency, transparency, and policy incentives. Moreover, the framework also acknowledges the fact that other organizational factors like financial limitations and involvement of stakeholders also affect the implementation of practices related to sustainability. Based on this, the model explains the outcomes of sustainability with reference to the regulatory drivers and issues to do with the implementation.

The suggested framework involves six major constructs such as regulatory stringency, transparency, policy incentives, financial constraints, stakeholder engagement, and sustainability outcomes. Sustainability outcomes are explained by regulatory stringency, transparency, and policy incentives. Financial Constraints is considered to be a strong organizational condition, and Stakeholder Engagement is considered to be in the center of the model. The framework is a logical explanation of how the sustainability practices are being formulated in the pharmaceutical organizations.

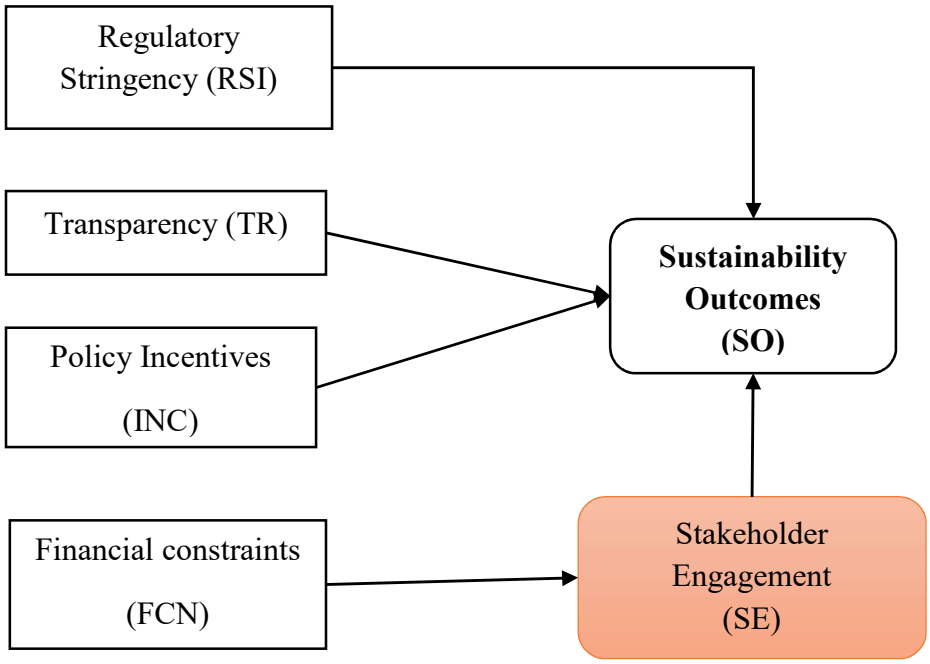

Figure 1: Conceptual Framework

H1: Regulatory Stringency

Institutional theory suggests that stronger regulatory pressure may encourage firms to align their practices with sustainability requirements. When regulatory expectations are more explicit and demanding, organizations may be more likely to adopt sustainability-oriented actions.

H1: Regulatory stringency is positively associated with sustainability outcomes.

H2: Transparency

Transparency improves disclosure, communication, and accountability, which can strengthen organizational commitment toward sustainability implementation. Greater openness in sustainability-related practices may therefore be associated with improved sustainability outcomes.

H2: Transparency is positively associated with sustainability outcomes.

H3: Policy Incentives

Policy incentives such as subsidies, support mechanisms, and regulatory encouragement may motivate firms to undertake sustainability-related initiatives. Such incentives are expected to support the adoption of sustainable practices and improve performance outcomes.

H3: Policy incentives are positively associated with sustainability outcomes.

H4: Stakeholder Engagement as Mediator

Financial constraints may affect how effectively organizations engage with stakeholders, coordinate sustainability-related actions, and mobilize support for implementation. In turn, stronger stakeholder engagement may contribute to better sustainability outcomes.

H4: Stakeholder engagement mediates the relationship between financial constraints and sustainability outcomes.

4. Research Methodology

4.1 Research Design and Approach

This paper assumed a mixed-method research design, which involves a quantitative analysis and qualitative interpretation in research to investigate the variables related to sustainability results in the pharmaceutical

industry. It was done by a deductive approach where the conceptual model and hypotheses were formulated based on the available literature and tested with primary data. The research was cross-sectional, where the data were gathered at one time among pharmaceutical professionals. This methodology assisted in creating both statistical and practical data on sustainability-based organizational practices.

4.2 Sample and Data Collection

The respondents were well diversified in terms of professional background and therefore provided legitimate information on the practice of sustainability and adherence to regulations. The data were collected using a structured questionnaire based on 5-point Likert scale (1 = strongly disagree, 5 = strongly agree) and an open-ended question was added to get the qualitative opinion on the regulatory practices, the governance mechanisms, and the adoption of sustainability. This kind of a two-tiered approach allowed integrating objective quantitative data with a rich narrative information source that may assist in comprehending the concept of institutional effectiveness in sustainable pharmaceutical regulation in a holistic manner.

4.3 Measurement of Variables

All variables were measured using multi-item scales on a 5-point Likert scale. The measurement framework includes both core regulatory constructs and analytically derived variables aligned with the conceptual model:

- Regulatory Stringency (RSI), Transparency (TR), Policy Incentives (INC), Stakeholder Engagement (SE), and Sustainability Outcomes (SO) represent the primary regulatory and governance constructs.
- Enforcement Consistency (EC) reflects the adequacy and regularity of monitoring and compliance enforcement.

Primary data was taken in the form of one hundred pharmaceutical professionals in key functional areas like regulatory affairs, quality assurance, manufacturing, and research and development. The participants of the sample were representative of the industry, as they represented organizations of different sizes and different product segments like vaccines, active pharmaceutical ingredients (APIs), and biologics.

- Financial Constraints (FCN) capture limitations related to budgetary resources and investment capabilities.

Additionally, control variables were included to account for confounding effects:

- Firm Size: Categorized as small (<100 employees) or large (>100 employees).
- Experience: Measured in years of professional experience.
- Sector Type: Represents different industry segments (e.g., vaccines, APIs, biologics).

Preliminary analysis showed moderate-to-high response levels, with **sustainability outcomes** showing the highest agreement, reflecting a strong commitment to sustainability practices.

4.4 Reliability and Validity

The scales proved to be reliable since the measurement tool had an excellent internal consistency of Cronbach's alpha = 0.951 when it was measured with 35 items (Table 1). Construction validity was also attained by aligning the items with the theoretical constructs that were proposed and cross-validating the quantitative data with the qualitative data that was obtained after administration of open-ended questions. This strict validation justifies the strength of the dataset for further statistical tests, which are regression, moderation, and mediation tests.

Table 1: Reliability Statistics

Cronbach's Alpha	N of Items
0.951	35

4.5 Data Analysis Techniques

Quantitative data were analyzed using SPSS to summarize the dataset, and identification of preliminary associations was employed to examine conditional relationships. The analysis proceeded in stages:

- The descriptive statistics were estimated to ascertain general trends of response and distribution of data.
- The direction and strength of relationships between the main constructs were tested with Pearson correlation analysis.
- The direct relationships between independent variables Regulatory Stringency (RSI), Transparency (TR), Policy Incentives (INC), Financial Constraints (FC), and Stakeholder Engagement (SE) and the dependent variable, Sustainability Outcomes (SO), were evaluated with the help of regression analysis. To minimize possible bias, control variables like firm size, professional experience, and sector type were used.
- Measurement and structural model were validated, latent construct reliability was measured, and path coefficients were estimated using the aid of Partial Least Squares Structural Equation Modeling (PLS-SEM) of SmartPLS. This approach will complement the SPSS analysis and address the complexity of models with the help of the available sample size.
- Coding of qualitative data was based on the logic of thematic analysis and identified trends of consistency of enforcement, financial constraints, governance mechanisms, and challenges of sustainability implementation.

Quantitative and qualitative results were combined, which provided the opportunity to have a more comprehensive view of the problem of institutional effectiveness, which combines the numerical with the context-specific knowledge and makes it easier to explain sustainability practices.

4.6 Methodological Justification

The chosen methodology is suitable since the study looks at the relationship between two or more latent constructs, which are measured using survey-based data. The initial statistical analysis was performed with the help of SPSS, and the SmartPLS was a suitable program to consider the revised conceptual model and indirect relationships with an intermediate sample size. The mixed-method approach additionally amplified the research by incorporating quantitative data with the contextual interpretation and consequently boosting the suitability and intelligibility of the findings.

5. Result and discussion

5.1 Descriptive statistics

To gain the overview of the key constructs and assess how the respondents perceived overall the practices concerning regulations and sustainability in the pharmaceutical industry, descriptive statistics were computed. It examined six constructs, i.e., Regulatory Stringency (RSI), Transparency (TR), Policy Incentives (INC), Financial Constraints (FCN), Stakeholder Engagement (SE), and Sustainability Outcomes (SO). Table 2 shows the average values and SD of these variables. The descriptive results show that there is moderate to high agreement of respondents on most of the constructs, which implies that there is generally a positive perception of sustainability-related practices and stakeholder-oriented processes in pharmaceutical organizations.

Table 2: Descriptive statistics

Construct	Mean	Std. Deviation
Regulatory Stringency (RSI)	3.314	0.527
Policy Incentives (INC)	3.978	0.986
Transparency (TR)	3.687	0.599
Stakeholder Engagement (SE)	4.010	0.899
Sustainability Outcomes (SO)	4.154	0.815
Financial Constraints (FCN)	1.928	0.811

The constructs that were retained had the highest mean (Sustainability Outcomes = 4.154, SD = 0.815), then Stakeholder Engagement (Mean = 4.010, SD = 0.899), and Policy Incentives (Mean = 3.978, SD = 0.986). These results show that the respondents were more likely to express a favorable opinion towards the sustainability-related outcomes, involvement of stakeholders, and support of the policy. The mean score of transparency was also moderately positive (mean = 3.687, SD = 0.599), as was the mean score of regulatory stringency (mean = 3.314, SD = 0.527), indicating that the respondents did not find regulatory requirements to be always stringent. The lowest mean score was Financial Constraints (Mean = 1.928, SD = 0.811), which shows the financial pressure in the sample was relatively low.

5.2 Correlation Analysis

Pearson correlation analysis was used to study the bivariate associations between the study constructs. The results indicate statistically significant correlations of the variables and are a preliminary pointer of the structural associations that would be considered in subsequent studies utilizing PLS-SEM. Table 3 is the correlation of regulatory stringency, policy incentives, transparency, stakeholder engagement, sustainability outcomes, and financial constraints.

Table 3: Correlation Matrix

Variable	RSI	INC	TR	SE	SO	FCN
Regulatory Stringency (RSI)	1	0.674**	0.552**	0.581**	0.542**	-0.506**
Policy Incentives (INC)	0.674**	1	0.765**	0.766**	0.738**	-0.758**
Transparency (TR)	0.552**	0.765**	1	0.841**	0.783**	-0.788**
Stakeholder Engagement (SE)	0.581**	0.766**	0.841**	1	0.839**	-0.886**
Sustainability Outcomes (SO)	0.542**	0.738**	0.783**	0.839**	1	-0.782**
Financial Constraints (FCN)	-0.506**	-0.758**	-0.788**	-0.886**	-0.782**	1

The correlations between sustainability outcomes and stakeholder engagement (r = 0.839), transparency (r = 0.783), and policy incentives (r = 0.738) are strong and positive. There is also a moderate positive relationship between regulatory stringency and sustainability outcomes (r = 0.542). On the other hand, the financial constraints are negatively correlated with all the other constructs, including stakeholder engagement (r = -0.886) and sustainability outcomes (r = -0.782), which shows that the more powerful the financial constraints are, the weaker the sustainability-related and stakeholder-related perceptions are. These are initial findings of the model in question, yet the observed relations can be considered as associations and not causal.

5.3 Measurement Model Assessment

The measurement model was assessed by examining indicator reliability and discriminant validity using the SmartPLS bootstrapping output. To test the measurement model, the reliability of the indicators and the discriminant validity were measured with the help of the SmartPLS bootstrapping output. The retained indicators were found to load fairly on the respective latent constructs, pointing to satisfactory indicator reliability. The outer loadings in the case of financial constraints took a range of between 0.679 and 0.851, and in the case of policy incentives, the loadings took a range of between 0.816 and 0.892. These values reveal that the indicators retained were enough to assess their own latent constructs in the revised model. The bootstrapping findings also revealed that the retained indicators were statistically significant and therefore had the trust of measurement items that were employed in the analysis.

The Heterotrait-Monotrait Ratio (HTMT) was used to determine the discriminant validity. Table 4 shows the

values of the HTMT of all the pairs of constructs. Some of the HTMT values were within acceptable ranges, and construct pair values were relatively high (even above the standard of 0.90). The values of the HTMT of stakeholder engagement-financial constraints in particular, transparency-stakeholder engagement, transparency-financial constraints, sustainability outcomes-stakeholder engagement, and transparency-sustainability This is an indication, though, that, although the revised model provides useful structural information, some of the constructs may be conceptually overlapping and should be approached carefully.

Table 4. Heterotrait-Monotrait Ratio (HTMT)

Construct Pair	HTMT
Policy Incentives – Financial Constraints	0.852
Regulatory Stringency – Financial Constraints	0.761
Regulatory Stringency – Policy Incentives	0.929
Stakeholder Engagement – Financial Constraints	1.006
Stakeholder Engagement – Policy Incentives	0.855
Stakeholder Engagement – Regulatory Stringency	0.813
Sustainability Outcomes – Financial Constraints	0.863
Sustainability Outcomes – Policy Incentives	0.821
Sustainability Outcomes – Regulatory Stringency	0.734
Sustainability Outcomes – Stakeholder Engagement	0.938
Transparency – Financial Constraints	0.957
Transparency – Policy Incentives	0.879
Transparency – Regulatory Stringency	0.808
Transparency – Stakeholder Engagement	1.000
Transparency – Sustainability Outcomes	0.929

The results of the HTMT show that in the current model, only discriminant validity is satisfactory. Even though there are pairs of constructs that are lower than the conservative value, the relatively high values of HTMT on the chosen pairs show that not all the constructs are totally different at the empirical level. In view of this, the structural relationships that are shown in the next section should be understood with a grain of salt, in particular, concerning the conceptually correlated variables, e.g., transparency, stakeholder engagement, and sustainability outcomes. PLS-SEM bootstrapping was used to test the hypothesized relationships between the retained constructs using the structural model. Figure 2 shows the standardized path coefficients of the estimated model of the structure.

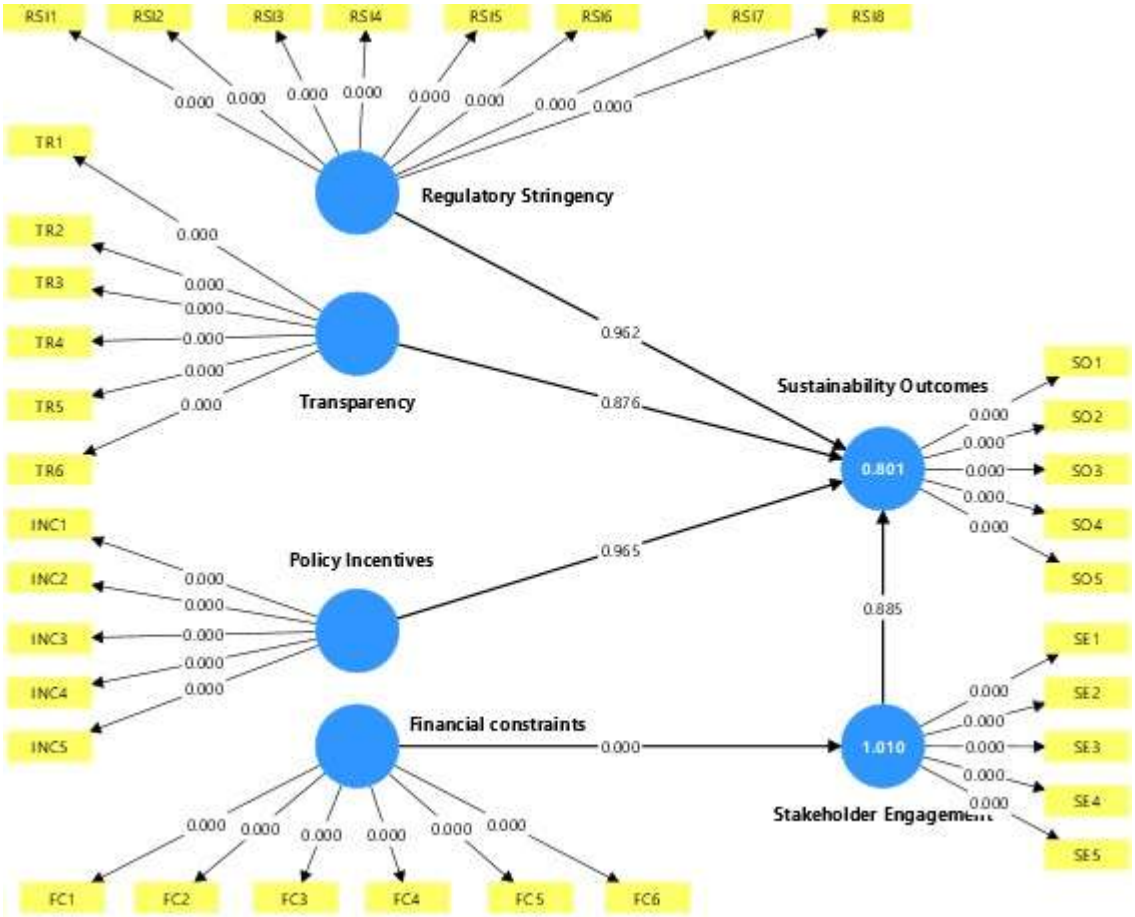

Figure 2. PLS-SEM Structural Model Showing Standardized Path Coefficients

Figure 2 shows that financial constraints and stakeholder engagement, stakeholder engagement and sustainability results, and transparency and sustainability results have positive and strong relationships, respectively, but the relationship between regulatory stringency and sustainability results is negative and insignificant. Table 5 shows the detailed significance levels, confidence level, and interpretation of these relationships.

PLS-SEM bootstrapping was done to assess the proposed framework. The structural model contained five direct relationships: financial constraints to stakeholder engagement, stakeholder engagement to sustainability outcomes, transparency to sustainability outcomes, policy incentives to sustainability outcomes, and regulatory stringency to Sustainability Outcomes. The results indicate three out of five of the direct paths are significant.

5.4 Structural Model Assessment

Table 5. Structural Path Coefficients

Path	β	STDEV	t-value	p-value
Financial Constraints → Stakeholder Engagement	0.886	0.024	36.898	0.000
Stakeholder Engagement → Sustainability Outcomes	0.419	0.159	2.634	0.008

Path	β	STDEV	t-value	p-value
Transparency → Sustainability Outcomes	0.369	0.154	2.395	0.017
Policy Incentives → Sustainability Outcomes	0.186	0.150	1.243	0.214
Regulatory Stringency → Sustainability Outcomes	-0.074	0.145	0.510	0.610

Financial Constraints and Stakeholders Engagement has a positive relationship, which is statistically significant (- = 0.886, t = 36.898, p = 0.000), and the interval between the two values does not include 0. Sustainability Outcomes is also positively and significantly related to Stakeholder Engagement (r = 0.419, t = 2.634, p = 0.008). Likewise, there is a good and statistically significant relationship between transparency and sustainability outcomes (r = 0.369, t = 2.395, p = 0.017). On the other hand, there are insignificant paths of the policy incentives to sustainability outcomes (0.186, p = 0.214) and the regulatory stringency to sustainability outcomes (-0.074, p = 0.610) due to the confidence intervals of the zeros. In this way, the structural model justifies the role played by financial constraints, stakeholder engagement, and transparency, and the direct relationship between policy incentives and regulatory stringency and sustainability outcomes is not justified in the current estimation.

Table 6. Effect Size (f^2) and R^2

Path	f^2 Effect Size	R^2 Value
Financial Constraints → Stakeholder Engagement	0.250 (Medium Effect)	$R^2 = 0.708$ (Stakeholder Engagement)
Stakeholder Engagement → Sustainability Outcomes	0.175 (Medium Effect)	$R^2 = 0.613$ (Sustainability Outcomes)
Transparency → Sustainability Outcomes	0.140 (Medium Effect)	

The values of the effect size (f 2) are used to suggest the practical meaning of the associations of the structural model. Stakeholder engagement had a medium effect (f 2 = 0.250) by financial constraints, indicating a significant impact on stakeholder engagement. Likewise, Stakeholder Engagement → Sustainability Outcomes was mediated with a medium effect (f 2 = 0.175), indicating that stakeholder engagement is an important factor in determining sustainability outcomes. Sustainability Outcomes Transparency also showed a medium impact (f 2 = 0.140), indicating the significance of transparency in influencing sustainability. The values of R 2 are the predictive power of the model, and the sustainability outcomes and stakeholder engagement explain 61.3 and 70.8 percent of the variance, respectively.

5.5 Indirect Effect Assessment

Since stakeholder engagement has a middle role between financial constraints and sustainability outcomes in the conceptual model, the indirect influence of financial constraints on sustainability outcomes via stakeholder engagement has been determined through bootstrapping. The correlation is positive and statistically significant (2.575 - 0.371 = 0.010, t = 2.575, p = 0.010), and the confidence interval does not lie in the range of 0. This implies that the financial constraints have a strong relationship with sustainability outcomes through stakeholder engagement.

Table 7. Indirect Effect

Indirect Path	β	STDEV	t-value	p-value	95% CI
Financial Constraints → Stakeholder Engagement → Sustainability Outcomes	0.371	0.144	2.575	0.010	[0.059, 0.632]

Financial constraints are positively and statistically significant in their total effect on sustainability outcomes (0.371, t = 2.575, p = 0.010), also justifying the importance of the indirect pathway through stakeholder engagement. Taken together, these findings indicate that stakeholder engagement plays a very important mediating role between financial constraints and sustainability outcomes in the hypothesized model.

6. Discussion

The results are a narrow insight into the dynamics that relate to the sustainability performance of pharmaceutical companies. Regarding the first hypothesis, H1 was not rejected since regulatory stringency was not observed to be statistically significantly related to sustainability outcomes (-0.074, p = 0.610). This shows that the existence of regulatory requirements might not be enough to achieve more sustainability results until it is enhanced by the effective organizational processes and implementation mechanisms. H2 was also accepted, and transparency was positively and significantly related to sustainability outcomes (0.369, p = 0.017). This means that the enhanced sustainability performance relates to the heightened disclosure, communication, and exposure of sustainability-related practices. Transparency and stakeholder engagement relationships are also high, and this justifies the importance of open governance practices in implementing sustainability.

H3 could not be supported by policy incentives, as no statistically significant correlation was found between policy incentives and sustainability outcomes (0.186, p = 0.214). Although the policy support was observed to be positively correlated with the sustainability outcomes at the correlation level, it was not significant in the structural model. This means that the policy-based performance that is based on the incentives might not be directly correlated with sustainability performance in case other organizational factors are put into consideration. The 4th hypothesis (H4) was accepted, with financial constraints demonstrating a strong positive association with stakeholder engagement (0.886, p = 0.001), and the mediating effect of financial constraints on sustainability outcomes by stakeholder engagement was also significant (0.371, p = 0.010). These findings indicate that stakeholder engagement plays a big mediating role in the model. Typically, transparency and stakeholder engagement as explained are the most emphasized mechanisms of sustainability outcomes in the revised framework.

7. Conclusion

This paper has looked into the relationship between regulatory and organizational elements and sustainability performance in the drug industry through an institutional effectiveness lens. The results show that regulatory pressure cannot explain sustainability performance, but it is a blend of governance-related and implementation-oriented processes. Among the examined dimensions, transparency seemed to be a significant positive factor that can be linked to sustainability performance, and more transparent disclosure, effective communication, and visibility of sustainability-related practices were found to be linked to the improved organizational sustainability performance. Sustainability outcomes and stakeholder engagement were also closely associated in a positive relationship, a factor that suggests that effective interaction and coordination of the stakeholders involved contribute a lot towards sustainability implementation. The results also demonstrate that financial constraints are not only closely related to the stakeholder engagement but also strongly indirectly affect the sustainability outcomes as a result of the stakeholder engagement. This implies that the financial condition factor in the

implementation of sustainability is more intricate than an obstacle in the form of a resource and can work via how companies organize and interact with stakeholders. On the other hand, policy incentives and regulatory stringency did not have a statistically significant direct relationship with sustainability outcomes in the structural model, although they had a positive relationship at the correlation level. This demonstrates that their effects may not be so direct and it may depend on organizational processes and situational circumstances.

Overall, the paper has demonstrated that the relationship between sustainability outcomes and transparency and stakeholder engagement in pharmaceutical companies is stronger in relation to regulatory pressure. These findings can supplement the more advanced notion of sustainability implementation by emphasizing the contribution of communication, stakeholder processes, and responsiveness of an organization to the achievement of significant sustainability results.

8. Practical Implications

The findings offer several implications for regulatory authorities, policymakers, and pharmaceutical firms:

- Regulatory authorities: The regulatory authorities must also prioritize not only stronger regulatory requirements but also improved support to implement the regulations, effective expectations on compliance, and improved reporting criteria to enhance the practice of sustainability.
- Transparency must be regarded as a strategic governance instrument, whereby clearer disclosure, communication, and accountability have a positive correlation with enhanced sustainability performance of pharmaceutical companies.
- Design of practical and accessible policy incentives: Policymakers ought to consider designing practical and accessible incentives since incentives in themselves might not necessarily enhance sustainability results without effective organizational processes and implementation capacity.
- Mechanisms of financial support, including subsidies, specific funding, and implementation support are critical, particularly to companies with limited resources that can influence the adoption of sustainability.
- Recommendations: Pharmaceutical organizations ought to enhance stakeholder engagement and internal coordination and invest in sustainability reporting and communication systems because stakeholder engagement was significantly positively related to sustainability outcomes.

9. Limitations and Future Scope

Although this research is significant in terms of understanding how regulatory and organizational issues impact the sustainability performance in the pharmaceutical industry, there are a few limitations to be considered when explaining the results.

- **Cross-sectional design:** The items were measured at a single point in time, and it is not possible to trace how the sustainability practices, the stakeholder engagement, and organizational responses would evolve with time. The future longitudinal studies may assist in providing a more accurate understanding of the changes over time and causal relationships.
- **Self-reported measures:** The research is based on self-reported data of pharmaceutical professionals. Although the instrument used was very reliable, there is a possibility that there was response bias and subjective perceptions in the associations among the reported constructs. Further research can improve the findings by employing more objective measures of organizations or sustainability.
- **Construct measurement limitations:** The results of the HTMT suggest that not all constructs, especially transparency, stakeholder engagement, and sustainability outcomes, might be entirely differentiable on the empirical level. This suggests that there may be a conceptual overlap and indicates that one should take the structural results with a grain of salt. Future research should enhance the measures to test the measurement scales on their own to enhance the distinctiveness of the constructs and the power of analysis.

Directions for future research:

- **Longitudinal research:** It is possible to consider that future research will take longitudinal designs to determine the changes in a sustainability practice and organizational mechanisms across time.
- **Cross-sector and cross-country research:** The comparative research with other industries and countries can be beneficial to the external validity of the results and highlight the differences in context.
- **Further measurement strategies:** Future work needs to come up with and test more discrete measures of the retained constructs.
- **Objective and technology-enabled metrics assimilation:** Digital reporting, objective sustainability metrics and application of technology-enabled monitoring devices could improve the accuracy of measurement.
- **Use of sophisticated analysis methods:** Future studies can expand on the modified model by incorporating more variables of organization and institution to further expound on the findings of sustainability.
- **Declarations**
- **Conflict of Interest**
- The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.
- **Availability of Data and Materials**
- The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.
- **Ethical Approval**
- This study was conducted in accordance with ethical standards for research involving human participants. As per institutional guidelines, formal ethical approval was not required for this study as it involved voluntary survey-based responses without sensitive personal data.
- **Accordance with Ethical Standards**
- All procedures performed in this study involving human participants were in accordance with the ethical standards of institutional and/or national research committees and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.
- **Consent to Participate**
- Informed consent was obtained from all individual participants included in the study. Participation was voluntary, and respondents were assured of anonymity and confidentiality.
- **Consent to Publish**
- The authors affirm that participants provided informed consent for anonymized data to be used for research and publication purposes. No identifiable personal information is included in this manuscript.
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- **AI Declaration**
- The authors declare that no generative AI tools were used in the writing, analysis, or interpretation of this research.

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