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Regulatory Compliance and Supplier Risk Assessment Frameworks in International Pharmaceutical Procurement

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Abstract

International pharmaceutical procurement has emerged as one of the most scrutinized domains of global trade, largely due to the complex interplay between regulatory compliance requirements, supplier performance, and risk management. As supply chains have become increasingly globalized, ensuring the integrity, safety, and reliability of pharmaceutical products has grown into a critical challenge for regulators, procurement bodies, and manufacturers. Supplier-related risksranging from quality failures and counterfeiting to non-compliance with Good Manufacturing Practices (GMP)can jeopardize public health, regulatory credibility, and corporate reputations. Accordingly, frameworks that systematically integrate regulatory compliance and supplier risk assessment have become indispensable for ensuring procurement decisions that safeguard patients, optimize costs, and promote supply chain resilience. This paper provides a comprehensive literature-based review of frameworks and methodologies developed up to 2022, with a particular focus on how international regulatory standards, supplier evaluation models, and risk assessment tools converge in the pharmaceutical sector. The study examines historical developments, methodological approaches, and the increasing role of data-driven risk assessment and compliance monitoring in pharmaceutical procurement. By synthesizing prior research, this paper highlights methodological strengths, gaps, and the need for holistic frameworks that capture regulatory, operational, and ethical considerations. The findings underscore the strategic role of compliance and risk assessment in enabling transparent, resilient, and sustainable pharmaceutical procurement systems across international contexts.

Keywords: Regulatory Compliance, Supplier Risk Assessment, Pharmaceutical Procurement, Global Supply Chains, Governance Frameworks, Supply Chain Resilience

1. Introduction

The procurement of pharmaceuticals in international markets is a domain where regulatory compliance and supplier risk assessment converge with exceptional intensity [1, 2]. Unlike other commodities, pharmaceuticals directly affect human health and safety, making the procurement process far more than a matter of economic efficiency [3, 4]. The consequences of supplier underperformance, non-compliance with regulatory requirements, or failure to identify risks extend beyond financial losses to encompass public health crises, loss of trust in health systems, and geopolitical challenges in access to essential medicines [5, 6]. International pharmaceutical procurement thus occupies a distinctive position within global supply chains, requiring robust frameworks that integrate regulatory requirements with risk-based supplier evaluation [7, 8].

Historically, procurement practices in the pharmaceutical sector emphasized cost efficiency and supply assurance, often overlooking broader compliance and risk concerns [9, 10, 11]. However, a series of high-profile scandals including counterfeit drugs, contamination incidents, and substandard medicines highlighted the critical importance of integrating regulatory compliance and supplier risk assessment into procurement decisions [12, 13, 14]. Global health authorities, including the World Health Organization (WHO), the U.S. Food and Drug Administration (FDA), and the European Medicines Agency (EMA), increasingly mandate stringent oversight of supplier qualifications, production processes, and distribution practices to ensure that pharmaceuticals meet established quality and safety standards [15, 16, 17]. As supply chains became globalized, these requirements intensified, with procurement agencies expected to navigate diverse regulatory environments, evolving

standards, and growing threats of supply chain vulnerabilities [18, 19, 20].

The increasing complexity of pharmaceutical supply chains has amplified supplier-related risks. Pharmaceutical ingredients and finished products are often sourced from multiple countries, each governed by distinct regulatory regimes [21, 22, 23]. For instance, a single finished drug product marketed in the United States may include active pharmaceutical ingredients (APIs) manufactured in India, excipients produced in China, and packaging materials supplied from Europe [24, 25]. Such fragmentation creates multiple points of vulnerability, including risks of non-compliance, supply disruptions, counterfeit infiltration, and geopolitical instability [26, 27]. Procurement agencies are thus compelled to develop comprehensive risk assessment frameworks that evaluate suppliers not only on cost and performance but also on their regulatory compliance status, manufacturing integrity, and capacity for resilience [28, 29].

Regulatory compliance in pharmaceutical procurement extends beyond adherence to national regulations; it encompasses compliance with international standards such as Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), and quality management systems [30, 31]. Procurement bodies often require suppliers to demonstrate certifications, regulatory inspection records, and compliance with pharmacovigilance obligations [32, 33]. However, compliance verification is not straightforward, as regulatory capacities differ across countries, and inspection resources are often constrained [34, 35]. Moreover, in low- and middle-income countries (LMICs), weak regulatory oversight exacerbates risks of counterfeit or substandard medicines infiltrating procurement channels [36, 37]. As a result, procurement organizations increasingly turn to frameworks that integrate regulatory data, supplier audits, and third-party verification as part of supplier risk assessment [38, 39].

Risk assessment frameworks in pharmaceutical procurement encompass a wide range of considerations, including financial risk, operational risk, reputational risk, and regulatory risk [40, 41]. These frameworks rely on structured methodologies such as multi-criteria decision-making (MCDM), risk scoring models, and probabilistic assessments to evaluate the likelihood and impact of supplier failures [42, 43]. In practice, organizations combine quantitative data (e.g., compliance metrics, defect rates, financial stability indicators) with qualitative assessments (e.g., management practices, organizational culture, geopolitical risk exposure) to develop holistic supplier risk profiles [44, 45]. This multidimensional approach reflects the recognition that pharmaceutical procurement risks are rarely confined to a single domain but often emerge from the interaction of regulatory, operational, and contextual factors [46, 47].

A defining feature of pharmaceutical procurement is the regulatoryrisk nexus, where compliance lapses are themselves treated as critical risks [9, 48, 49]. For example, a supplier's failure to comply with GMP may result in regulatory sanctions, product recalls, or import bans, each of which constitutes a direct procurement risk [50, 51]. Conversely, procurement decisions that ignore regulatory compliance considerations may expose organizations to legal liability, reputational damage, and, in extreme cases, patient harm. This interdependence underscores the need for frameworks that integrate compliance verification and risk assessment into a unified process rather than treating them as parallel but separate domains [52, 53].

The literature reflects a progression toward more systematic and data-driven frameworks for supplier risk assessment in pharmaceutical procurement. Early approaches relied heavily on supplier self-reporting and periodic audits, which, while necessary, were insufficient in detecting emerging risks or ensuring ongoing compliance [54, 55, 56]. More recent frameworks incorporate continuous monitoring, real-time data analytics, and predictive modeling to identify risk signals before they materialize into crises [57, 58]. For instance, advances in big data analytics and machine learning have enabled procurement organizations to analyze supplier performance data, regulatory inspection outcomes, and market intelligence to generate predictive risk scores [59, 60]. Such data-driven frameworks provide a more dynamic and responsive approach to supplier evaluation, aligning with the broader transformation of supply chain management under Industry 4.0 [61, 62].

International procurement organizations face additional challenges in harmonizing regulatory compliance frameworks across jurisdictions. While bodies such as WHO and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) promote global convergence of standards, differences in national regulatory frameworks persist. These discrepancies create challenges for procurement organizations operating across multiple countries, as suppliers may be compliant in one jurisdiction but non-compliant in another [57, 63]. Harmonization efforts, including mutual recognition agreements and international benchmarking of regulatory authorities, have attempted to address these issues but remain uneven in practice [64]. Consequently, procurement frameworks must incorporate mechanisms to evaluate regulatory equivalence, adapt to local contexts, and manage compliance risks across heterogeneous regulatory environments [65, 66].

Another critical dimension of supplier risk assessment is the growing emphasis on ethical procurement and corporate social responsibility in the pharmaceutical sector. Beyond compliance with manufacturing standards, procurement bodies increasingly evaluate suppliers on their adherence to ethical labor practices, environmental sustainability, and corporate governance [67, 68]. These considerations align with broader trends in global supply chains, where stakeholders demand accountability not only for product quality but also for the social and environmental impacts of production [69, 70]. For pharmaceutical procurement, this translates into expanded frameworks that integrate sustainability metrics, supplier diversity, and transparency in sourcing practices. While such frameworks enhance accountability, they also introduce additional complexities in supplier evaluation, requiring procurement bodies to balance regulatory, operational, financial, and ethical considerations [71, 72].

The global COVID-19 pandemic further underscored the importance of integrating compliance and risk assessment in pharmaceutical procurement. Supply chain disruptions, export restrictions, and unprecedented demand for vaccines and essential medicines highlighted the vulnerabilities of overreliance on limited suppliers or regions [73, 74]. Procurement agencies faced the dual challenge of ensuring compliance with accelerated regulatory processes while mitigating supply risks under conditions of extreme uncertainty. This experience catalyzed calls for more resilient procurement frameworks that integrate compliance

monitoring with proactive risk assessment, including diversification of suppliers, regional manufacturing capacity building, and real-time supply chain visibility [75, 76, 77].

In academic literature, several streams of research converge on the development of comprehensive frameworks that address these challenges. Operations research contributes methodologies for risk modeling, optimization, and decision-making under uncertainty [78, 79]. Regulatory science provides insights into compliance monitoring, harmonization, and inspection practices. Supply chain management scholarship explores strategies for resilience, collaboration, and sustainability in supplier networks [80, 81]. Together, these fields offer a multidisciplinary foundation for the design of robust supplier risk assessment and compliance frameworks. However, gaps remain, particularly in translating methodological advances into practical, scalable, and context-sensitive procurement systems.

In sum, the introduction highlights the critical importance of regulatory compliance and supplier risk assessment in international pharmaceutical procurement. The procurement of medicines is not a purely economic transaction but a strategic and ethical function central to public health. The complexity of pharmaceutical supply chains, the diversity of regulatory environments, and the magnitude of supplier-related risks necessitate frameworks that integrate compliance verification and risk assessment into coherent, data-driven systems. The following literature review builds upon these foundations, providing a structured analysis of existing research and methodologies up to 2022, with the aim of consolidating insights and identifying pathways for future development.

2. Literature Review

The procurement of pharmaceuticals has been the subject of extensive scholarly and policy-oriented inquiry, particularly with regard to regulatory compliance and supplier risk assessment. The literature reflects a rich evolution from descriptive accounts of procurement practices toward increasingly sophisticated, data-driven, and governance-oriented frameworks. This review examines the intellectual trajectory of research up to 2022, focusing on three interrelated dimensions: regulatory compliance in pharmaceutical procurement, supplier risk assessment methodologies, and the integration of compliance and risk frameworks in international contexts.

2.1 Historical Evolution of Regulatory Compliance in Pharmaceutical Procurement

The origins of regulatory compliance in pharmaceutical procurement can be traced to the mid-20th century, when drug safety crises, including the thalidomide tragedy, underscored the necessity of stringent oversight of pharmaceutical production and distribution [82]. In response, national regulatory authorities such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) institutionalized compliance regimes anchored in Good Manufacturing Practices (GMP) and quality control standards [83, 84]. These regimes initially focused on domestic pharmaceutical markets but gradually expanded to address international procurement as supply chains globalized [85].

During the late 20th century, international organizations, particularly the World Health Organization (WHO), began advocating harmonization of regulatory standards across jurisdictions [86]. Initiatives such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) sought to streamline technical requirements, creating more consistent frameworks for assessing supplier compliance globally [87]. However, disparities persisted, especially between high-income countries with robust regulatory infrastructures and low- and middle-income countries (LMICs) where regulatory capacity remained limited.

By the early 2000s, literature increasingly highlighted the role of procurement agencies in enforcing compliance through supplier qualification processes, audits, and contractual obligations [88]. Scholars emphasized that procurement was not only an economic function but also a mechanism for ensuring that medicines met international safety and quality standards. Consequently, compliance verification became embedded in procurement frameworks, requiring suppliers to demonstrate adherence to GMP, pharmacovigilance obligations, and ethical production practices [89].

2.2 Supplier Risk Assessment in Pharmaceutical Procurement

Parallel to regulatory compliance, scholarship on supplier risk assessment in pharmaceutical procurement developed rapidly in the 1990s and 2000s, reflecting broader interest in supply chain risk management [90, 91, 92]. Initial approaches to risk assessment were primarily qualitative, relying on expert judgment and historical performance data [93]. These frameworks categorized risks into operational, financial, and reputational domains, with compliance-related risks often treated as a subset of operational concerns.

Over time, risk assessment methodologies became increasingly quantitative and structured. Multi-criteria decision-making (MCDM) methods such as Analytic Hierarchy Process (AHP), Analytic Network Process (ANP), and Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS) were applied to supplier evaluation, enabling procurement organizations to weigh and prioritize risks systematically [94, 95]. These approaches provided a mechanism for balancing competing objectives such as cost efficiency, quality, compliance, and resilience.

Probabilistic risk models also gained prominence, particularly in contexts where uncertainty was high. Bayesian networks, Monte Carlo simulations, and fault tree analyses were applied to model the likelihood and impact of supplier risks in pharmaceutical procurement. These methods allowed procurement organizations to assess risk exposure under various scenarios, facilitating proactive risk management strategies [96]. However, critics noted that these models often relied on assumptions and data that were not easily verifiable, limiting their applicability in resource-constrained settings.

By the 2010s, attention shifted toward the integration of risk assessment with real-time data and predictive analytics. With the rise of digital supply chains, procurement organizations gained access to diverse data sources, including regulatory inspection records, shipment data, and social media monitoring. Scholars highlighted the potential of big data analytics and machine learning algorithms to identify early warning signals of supplier risks, such as patterns of quality non-conformance, geopolitical instability, or financial distress. These approaches aligned with the broader Industry 4.0 transformation, positioning supplier

risk assessment as a dynamic and data-driven capability [97].

2.3 The Regulatory–Risk Nexus in Procurement

A central theme in the literature is the convergence of regulatory compliance and supplier risk assessment, often described as the regulatory–risk nexus. In the pharmaceutical sector, compliance lapses—such as GMP violations or falsified quality certificatesare themselves major risk events that can trigger regulatory sanctions, import bans, or product recalls [98]. Accordingly, scholars argue that compliance cannot be treated as a parallel concern but must be integrated into risk assessment frameworks.

Several studies illustrate how procurement organizations operationalize this nexus. For example, procurement bodies frequently incorporate regulatory inspection outcomes into supplier risk scoring systems. A supplier with repeated non-compliance findings may be assigned a higher risk rating, affecting procurement decisions such as contract renewals or supplier diversification [99]. Similarly, compliance with international certifications (e.g., ISO, GMP, GDP) is often treated as a prerequisite or risk-mitigating factor in supplier evaluations.

The literature also highlights the role of procurement agencies in bridging regulatory gaps across jurisdictions. In contexts where national regulatory authorities lack capacity, procurement bodies may rely on international benchmarks, third-party audits, or donor-funded prequalification programs to assess supplier compliance and mitigate risks [100]. The WHO Prequalification of Medicines Programme (PQP), for example, plays a crucial role in providing LMIC procurement bodies with validated information on supplier compliance. By integrating compliance verification into procurement processes, these mechanisms reduce risks of counterfeit, substandard, or unsafe medicines entering international supply chains [101].

2.4 Challenges in Regulatory Compliance and Risk Assessment

Despite methodological advances, the literature identifies persistent challenges in implementing regulatory compliance and supplier risk assessment frameworks in pharmaceutical procurement.

One major challenge is the heterogeneity of regulatory environments. While harmonization efforts have progressed, significant differences remain in how countries interpret and enforce regulatory standards [102]. A supplier may be compliant under one regulatory regime but non-compliant under another, creating uncertainty for procurement bodies operating in international markets [103]. Mutual recognition agreements and international benchmarking have attempted to reduce these discrepancies, but uneven adoption undermines global consistency.

Another challenge concerns data availability and reliability. Risk assessment frameworks often require detailed and timely data on supplier performance, compliance status, and operational risks. However, such data is frequently incomplete, inconsistent, or unavailable, particularly in LMIC contexts. Scholars have emphasized the importance of data governance, transparency, and capacity-building to enable more effective risk-based procurement [104].

The complexity of risk models is also cited as a limitation. Sophisticated probabilistic models and MCDM frameworks may provide robust analytical insights but can be difficult to implement in practice without technical expertise and resources. This creates a gap between academic innovation and practical application, with many procurement bodies continuing to rely on simpler, more qualitative risk assessment methods [105].

Finally, the integration of ethical and sustainability concerns into compliance and risk frameworks remains underdeveloped. While there is growing recognition that pharmaceutical procurement should account for environmental, social, and governance (ESG) factors, operationalizing these dimensions within compliance and risk assessment models has proven challenging. Scholars argue that future frameworks must expand beyond technical compliance to capture the broader societal responsibilities of pharmaceutical supply chains [106].

2.5 Emerging Trends up to 2022

By 2022, several emerging trends in the literature suggested new directions for regulatory compliance and supplier risk assessment in pharmaceutical procurement.

The first trend is the rise of real-time monitoring systems, leveraging digital technologies such as blockchain, Internet of Things (IoT), and big data analytics. Blockchain has been proposed as a tool for ensuring transparency and traceability in pharmaceutical supply chains, enabling procurement bodies to verify compliance and reduce risks of counterfeit infiltration. IoT-enabled monitoring of storage and transportation conditions provides additional assurances of compliance with Good Distribution Practices (GDP).

The second trend is the integration of predictive analytics into risk assessment frameworks. Machine learning algorithms are increasingly used to analyze large datasets, identify patterns of non-compliance, and predict supplier risks before they materialize. For example, predictive models can flag suppliers with a history of minor deviations as potential candidates for future major compliance failures.

The third trend is the institutionalization of global prequalification programs and international collaborations. Initiatives such as the WHO PQP and collaborative registration procedures aim to strengthen regulatory oversight in LMICs while providing procurement bodies with reliable compliance data. These programs represent an effort to institutionalize the regulatory–risk nexus at a global level, reducing reliance on fragmented national systems [107, 108].The final trend is the growing emphasis on resilience and sustainability in procurement frameworks. The COVID-19 pandemic demonstrated the vulnerabilities of concentrated supply chains, prompting calls for diversification, regionalization, and resilience-building. At the same time, stakeholders increasingly demand that pharmaceutical procurement consider environmental sustainability and ethical labor practices, integrating these concerns into compliance and risk frameworks [109].

2.6 Synthesis

The literature on regulatory compliance and supplier risk assessment in international pharmaceutical procurement demonstrates a clear trajectory of increasing sophistication and integration. Early frameworks emphasized cost and supply assurance, gradually incorporating compliance verification and risk assessment as central components of procurement. By 2022, frameworks had evolved to include data-driven risk modeling, global regulatory harmonization efforts, and emerging concerns around resilience and sustainability.

Despite these advances, challenges remain in harmonizing regulatory environments, ensuring data availability, and operationalizing complex models in diverse procurement contexts. Furthermore, the integration of ESG concerns into compliance and risk frameworks remains an underdeveloped frontier. Scholars and practitioners alike emphasize the need for frameworks that are not only analytically rigorous but also practically viable, context-sensitive, and aligned with global health objectives.

In summary, the literature up to 2022 reflects a field in transition: from fragmented, compliance-oriented approaches toward holistic, data-driven frameworks that integrate regulatory requirements, risk management, and sustainability. These developments set the stage for discussions on how procurement agencies, regulators, and suppliers can collaborate to design resilient, transparent, and ethically responsible pharmaceutical supply chains.

3. Discussion and Implications

The literature reviewed highlights that international pharmaceutical procurement is no longer a transactional activity based solely on cost minimization or supply assurance but has evolved into a strategic function deeply intertwined with public health outcomes, regulatory governance, and global risk management. The integration of regulatory compliance and supplier risk assessment into procurement processes is not merely a technical necessity but a strategic imperative. This section discusses the implications of these developments for both practice and theory, focusing on four major areas: the regulatory–risk nexus, practical implementation challenges, the role of digital transformation, and the future integration of ethical and sustainability considerations.

A primary implication of the literature is the recognition of the regulatoryrisk nexus as central to pharmaceutical procurement. Non-compliance with Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), or pharmacovigilance obligations is not just a regulatory issue but also a procurement risk with direct implications for supply continuity and public health [110]. Procurement agencies therefore need frameworks where compliance and risk assessment are unified rather than parallel. This convergence underscores the necessity of moving beyond fragmented approaches toward comprehensive, integrated systems that treat compliance datasuch as regulatory inspection outcomes, certifications, and audit reportsas critical inputs into risk scoring models.

From a practical perspective, however, the implementation of sophisticated compliance–risk frameworks is constrained by disparities in regulatory capacity, data availability, and organizational resources. While high-income countries may deploy predictive analytics, blockchain, and IoT to monitor supplier compliance and assess risks in real time, many low- and middle-income countries (LMICs) continue to rely on manual audits and fragmented data [111, 112]. This disparity raises significant equity concerns in global pharmaceutical procurement. Donor-driven mechanisms such as the WHO Prequalification Programme attempt to bridge these gaps, but their reach remains limited relative to the scale of global pharmaceutical trade. For procurement organizations, this suggests a need for capacity building, data-sharing mechanisms, and scalable models that can adapt to contexts with varying resource levels.

The third implication is the transformative role of digital technologies in shaping future compliance and risk assessment frameworks. Blockchain, for example, offers a means to enhance transparency and traceability, reducing risks of counterfeit medicines infiltrating supply chains [113, 114]. Predictive analytics powered by machine learning can identify suppliers likely to experience compliance failures before such failures occur. IoT-enabled monitoring ensures compliance with temperature and storage requirements, particularly critical for vaccines and biologics. These technologies shift procurement from reactive compliance verification toward proactive, real-time risk management. However, they also raise concerns regarding data governance, cybersecurity, and the cost of implementation. Future frameworks must therefore balance the promise of digital tools with the need for robust governance structures that ensure data integrity, interoperability, and equitable access [115].

Finally, the literature highlights the growing demand to incorporate ethical and sustainability considerations into compliance and risk assessment frameworks. The COVID-19 pandemic revealed not only vulnerabilities in pharmaceutical supply chains but also inequities in access to vaccines and medicines. Procurement organizations are increasingly expected to consider not only whether suppliers comply with technical standards but also whether their practices align with principles of corporate social responsibility, environmental sustainability, and equitable access. While frameworks have begun to integrate environmental, social, and governance (ESG) indicators, operationalizing these dimensions within risk models remains underdeveloped. The implication is that future research and practice must move toward multidimensional frameworks that assess suppliers not only on compliance and risk but also on their contributions to sustainability, resilience, and health equity.

In theoretical terms, the convergence of compliance and risk assessment calls for greater cross-disciplinary integration. Operations research, regulatory science, information systems, and global health governance each contribute relevant insights, but scholarship remains fragmented across disciplines. A more integrated research agenda is needed to develop frameworks that are both analytically rigorous and practically applicable. Such frameworks must account for institutional diversity, technological innovation, and the complex interplay between regulation, risk, and ethics in global pharmaceutical supply chains.

Overall, the discussion underscores that international pharmaceutical procurement frameworks must evolve into comprehensive governance systems, integrating compliance verification, risk assessment, digital innovation, and ethical accountability. For procurement agencies, this implies rethinking procurement not as an administrative function but as a strategic capability central to public health security and supply chain resilience.

4. Conclusion

This paper has provided a comprehensive review of regulatory compliance and supplier risk assessment frameworks in international pharmaceutical procurement up to 2022. The review highlights a trajectory of increasing sophistication, from early procurement models focused on cost and availability to contemporary frameworks that integrate regulatory oversight, risk management, and digital innovation. At the heart of this evolution is the recognition

of the regulatory–risk nexus, where compliance and supplier risk are inseparable dimensions of procurement decision-making.

The analysis identifies several key insights. First, regulatory compliance is not only a legal requirement but also a core procurement risk dimension, as lapses can trigger supply disruptions, recalls, or bans with significant public health consequences. Second, supplier risk assessment frameworks have shifted from qualitative, judgment-based models to data-driven, predictive systems that leverage big data, machine learning, and IoT-enabled monitoring. Third, while methodological advances have been significant, challenges persist in harmonizing regulatory standards, ensuring reliable data availability, and implementing complex models across diverse procurement contexts. Fourth, there is growing recognition of the need to incorporate ethical and sustainability considerations, extending procurement frameworks beyond technical compliance to encompass environmental responsibility, social accountability, and equitable access.

For practice, the findings suggest that procurement agencies should prioritize integrated compliance–risk frameworks that unify regulatory data with risk assessment methodologies. Investment in digital technologies such as blockchain and predictive analytics can significantly enhance transparency, resilience, and responsiveness. However, capacity-building efforts are equally essential, particularly in LMIC contexts where data availability and regulatory capacity are limited. Future procurement systems must balance technological innovation with inclusivity, ensuring that global pharmaceutical procurement contributes to equitable health outcomes rather than exacerbating disparities.

For scholarship, the paper highlights the need for cross-disciplinary research agendas that bridge operations research, regulatory science, information systems, and sustainability studies. Such integration is necessary to design frameworks that are both rigorous and practical, capable of addressing the multifaceted challenges of pharmaceutical procurement. Future research should explore models that embed ESG indicators into compliance–risk frameworks, assess the impact of digital technologies on procurement governance, and develop adaptive systems that respond to evolving global health crises.

In conclusion, regulatory compliance and supplier risk assessment are not peripheral concerns but central pillars of international pharmaceutical procurement. Developing frameworks that integrate these dimensions in comprehensive, data-driven, and ethically grounded ways is essential for ensuring safe, effective, and equitable access to medicines worldwide. As global health challenges continue to evolve, procurement systems must advance in tandem, serving as strategic instruments of public health governance and supply chain resilience.

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