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Regulating Digital Pharmacies in Malaysia: Lessons from the United States

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Abstract

E-commerce has experienced rapid growth, and access to pharmaceutical products has changed, raising questions about unauthorised online sales and platform responsibility. Malaysia lacks comprehensive pharmaceutical legislation for digital intermediaries. By comparison, the United States takes a complex regulatory approach that includes federal drug regulations and market-based transparency requirements. This study employs doctrinal and comparative approaches to assess the adequacy of Malaysia's regulatory framework. The findings highlight fragmented enforcement and weak platform responsibilities, underscoring the need for reforms to improve verification, traceability, and consumer protection.

Keywords: : E-commerce; Pharmaceutical products; Online platform liability; Digital health regulation.

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1.0 Introduction

The growth of online business, specifically in e-commerce, has altered the distribution of pharmaceutical products worldwide. Over 70% of Malaysian consumers are online buyers of even health-related products (New Straits Times, 2023). While digital platforms provide convenience and wider market access, they also introduce substantial risks, particularly the proliferation of unregistered medicines, counterfeit drugs, and unauthorised sellers operating outside professional supervision (Ahmed et al., 2022; Mackey & Nayyar, 2016). During Operation Pangea XVII (2025), INTERPOL reported seizures of approximately USD 65 million worth of illicit pharmaceuticals, alongside 769 arrests and the disruption of 123 criminal networks (INTERPOL, 2025). In 2025, Malaysia removed approximately 7,000 online pharmaceutical listings (Lim & Yang, 2025). These statistics reveal that online pharmaceutical risks represent a structural regulatory challenge rather than isolated misconduct.

Malaysia's pharmaceutical regulatory framework, including the Poisons Act 1952 (PA 1952), the Sale of Drugs Act 1952 (SODA 1952), the Control of Drugs and Cosmetics Regulations 1984 (CDCR 1984), and the Medicines (Advertisement and Sale) Act 1956 (MASA 1956), establishes strict controls over registration, licensing, and advertising. However, Malaysia developed these laws within a traditional brick-and-mortar regulatory model and remains only partially adapted to digital environments. In particular, the framework relies predominantly on disclosure-based obligations and lacks explicit statutory duties requiring platforms to verify the legality of pharmaceutical sellers. This framework creates a regulatory gap that enables anonymity, cross-border operations, and repeated re-entry of unauthorised sellers.

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Conceptually, this study is informed by the evolving understanding of digital platforms as active market intermediaries, or "gatekeepers", rather than passive conduits of third-party content. Platforms influence market behaviour by controlling access, visibility, and transactions. In high-risk sectors such as pharmaceuticals, this shift requires a reconsideration of regulatory responsibility. However, Malaysia's current framework does not fully reflect this transformation, leading to a misalignment between regulatory design and the realities of the digital market.

In contrast, the United States adopts a more layered regulatory approach, combining pharmaceutical control laws with platform-related measures, including identity verification requirements under the INFORM Consumers Act 2023. This situation provides a useful comparative model for assessing regulatory adaptation in digital contexts.

Accordingly, this study evaluates the adequacy of Malaysia's legal framework governing pharmaceutical e-commerce, focusing on platform accountability and seller traceability. It further examines whether disclosure-based regulation is sufficient or whether verification-based obligations are required. The study pursues three objectives: (i) to analyse Malaysia's current legal framework; (ii) to examine the United States' regulatory approach; and (iii) to propose calibrated reforms to strengthen digital pharmaceutical governance.

2.0 Literature Review

2.1 Pharmaceutical Online Risks

The expansion of e-commerce has significantly reshaped the distribution of pharmaceutical products, but academic literature consistently identifies online pharmaceutical markets as inherently high-risk. While digital platforms enhance accessibility and convenience, they also weaken traditional regulatory safeguards that rely on physical oversight and licensed intermediaries (Ahmed et al., 2022; Mackey & Nayyar, 2016). Scholars emphasise that digital marketplaces reduce entry barriers, enabling unauthorised actors to distribute counterfeit, substandard, or unregistered medical products without meeting regulatory requirements (Mackey & Liang, 2013; Liang & Mackey, 2009). Online sellers benefit from anonymity and cross-border reach, enabling rapid re-entry after enforcement actions that undermine mechanisms designed for identifiable actors. The issue, therefore, reflects a broader misalignment between regulatory design and digital market realities, rather than isolated non-compliance.

An empirical study reports that a substantial proportion of prescription medicines available on e-marketplaces are not registered with regulatory authorities, indicating weaknesses in pre-market controls (Alphonsoes et al.,2021). This study suggests that online platforms function as alternative distribution channels that bypass established safeguards. Non-compliance risks intensified during the COVID-19 pandemic, when increased demand created opportunities for counterfeit product sellers (Ahmed et al., 2022).

From a public health perspective, these risks are particularly serious. The World Health Organisation (2026) highlights that online marketplaces facilitate the circulation of unsafe medical products without adequate regulatory oversight. Given that pharmaceutical products directly affect patient safety, scholars argue that regulatory approaches designed for general consumer goods are inadequate in this context. Instead, stronger mechanisms, including verification and professional accountability, are required (Mackey & Liang, 2013).

However, despite extensive documentation of risks, the literature remains largely descriptive. It focuses on identifying harms rather than evaluating whether existing legal frameworks are structurally capable of addressing these risks in digital environments. In particular, past studies provided limited attention as to how regulatory systems should adapt to e-marketplace platforms. This review reveals a key gap: the lack of analysis of how regulatory design should evolve in response to the structures of digital marketplaces.

2.2 Platform Governance and Intermediary Responsibility

A recent study has shifted from a product-focused analysis of pharmaceutical risks to a platform-centric perspective. Traditional legal approaches conceptualised online intermediaries as passive conduits of third-party content, with liability arising primarily through notice-and-takedown mechanisms. However, this characterisation has increasingly been challenged.

Contemporary studies demonstrate that e-commerce platforms play an active role in structuring market behaviour. Platforms organise transactions, determine product visibility through algorithmic ranking, facilitate payment systems, and regulate access to sellers (Fairgrieve et al., 2024). These functions indicate that platforms are not neutral intermediaries but active market participants, raising questions regarding the allocation of regulatory responsibility.

This shift has prompted a re-evaluation of traditional legal doctrines, particularly those derived from product liability and intermediary immunity frameworks. Scholars argue that these doctrines, developed in physical market contexts, are insufficient to address platform-mediated environments (Fairgrieve et al., 2024). As a result, an emerging regulatory discourse is advocating a shift from post hoc liability to ex ante governance mechanisms, including seller verification, transparency, and traceability.

Legislative developments, such as the INFORM Consumers Act 2023 in the United States, reflect this transition by introducing identity verification requirements to reduce anonymity in online trade (Brannon & Holmes, 2024). These developments signal a broader shift toward recognising platforms as regulatory "gatekeepers" with preventive responsibilities, particularly in high-risk sectors.

In contrast, Malaysia's regulatory framework remains grounded in general consumer protection and electronic commerce laws, such as the Electronic Commerce Act 2006 and the Consumer Protection Act 1999, which emphasise disclosure and contractual fairness. While these mechanisms promote transparency, scholars argue that they are insufficient in high-risk sectors such as pharmaceuticals, where harm extends beyond economic loss to patient safety (Mackey & Liang, 2013; Fairgrieve et al., 2024). Reliance on disclosure without verification raises concerns about regulatory effectiveness.

Although statutory pharmaceutical controls remain robust in jurisdictions such as Malaysia and the United States, there is limited integration between sector-specific regulation and platform governance mechanisms. This disconnect highlights a key gap in the literature, particularly in understanding the calibration of regulatory responsibility in platform-mediated environments. Accordingly, this study adopts a comparative and functional approach to examine how different legal systems allocate intermediary responsibility in pharmaceutical e-commerce, with a view to identifying appropriate reforms for Malaysia.

3.0 Methodology

This study adopts a qualitative, doctrinal, and comparative legal methodology to evaluate the adequacy of the regulatory frameworks governing pharmaceutical e-commerce in Malaysia. Doctrinal research remains the core method in legal scholarship, involving the systematic analysis of legal materials to examine existing legislation, identify inconsistencies, and support legal reform. Developed through centuries of judicial and legal practice, it focuses on the identification, interpretation, and application of legal rules to practical situations. This approach relies primarily on authoritative sources, including legislation and case law, supported by academic literature (Hutchinson & Duncan, 2012). A comparative legal approach complemented doctrinal analysis to identify functionally relevant regulatory mechanisms.

To ensure analytical clarity, the study applies a structured functional analytical framework based on four evaluative criteria. First, verification mechanisms, which assess whether the legal framework imposes ex ante obligations on platforms or sellers to authenticate the legitimacy of pharmaceutical transactions. Second, traceability and identity persistence, which evaluate the extent to which legal rules enable the identification and tracking of sellers, including safeguards against anonymity and repeated re-entry. Third, intermediary responsibility, which examines the degree to which platforms are assigned active regulatory roles, including monitoring, compliance enforcement, and risk control. Fourth, enforcement coordination, which assesses the level of institutional integration, including data-sharing mechanisms, inter-agency cooperation, and responsiveness to cross-border violations.

These criteria serve as evaluative benchmarks to determine whether each jurisdiction adopts a predominantly reactive model, relying on post-listing enforcement, or a preventive model that incorporates pre-transaction safeguards. The comparative analysis follows a functional method, focusing on how each legal system addresses similar regulatory risks rather than formal legal differences.

The research employed library and online legal sources. Primary materials include statutory laws and regulatory instruments in Malaysia and the United States. Some of the Malaysian pharmaceutical laws and consumer laws examined include PA 1952, SODA 1952, CDCR 1984, MASA 1956, the Consumer Protection Act 1999 and the Consumer Protection (Electronic Trade Transactions) Regulations 2024. Meanwhile, for the United States, the statutes that were examined are the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act), the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act), and the INFORM Consumer Act of 2023. In addition, secondary sources include academic literature, policy reports, and enforcement data such as Operation Pangea.

The analysis proceeds in two stages: first, a doctrinal analysis to establish the legal position in each jurisdiction; and second, a comparative evaluation based on the identified criteria to assess regulatory effectiveness and identify reform opportunities. Although the study does not incorporate empirical data, this structured and criteria-based approach enhances analytical rigour, transparency, and replicability.

4.0 Findings

4.1 Malaysia: Substantive Strength with Digital Gaps

Malaysia's pharmaceutical regulatory framework is substantively strong and grounded in public health protection. Statutes such as PA 1952, SODA 1952, and CDCR 1984 impose strict requirements on product registration, licensing, and advertising. Pharmaceutical products must be registered with the Drug Control Authority, and prescription medicines may only be supplied by authorised professionals. This situation reflects a process-based regulatory approach prioritising safety, efficacy, and professional control (Zuryani et al., 2021).

The framework functions effectively in traditional settings, where licensed premises are subject to routine inspections and clear enforcement actions such as seizure and prosecution. However, the shift to e-commerce exposes structural limitations. Online platforms enable rapid seller entry, anonymity, and cross-border transactions, complicating regulatory control (Lim & Abdul Aziz, 2025; Mackey & Nayyar, 2016). Although the sale of unregistered or prescription medicines without authorisation is illegal, Malaysian law does not impose explicit verification duties on platforms.

This lack of platform-facing accountability weakens enforcement. Regulatory responsibilities are fragmented across multiple agencies, leading to coordination challenges and delays in digital investigations. Cross-border transactions further complicate jurisdiction and evidence collection (Lim & Abdul Aziz, 2025). While consumer protection laws require disclosure of seller information, they do not mandate verification of licensing status (Consumer Protection Act 1999; Consumer Protection (Electronic Trade Transactions) Regulations 2024). As a result, enforcement remains largely reactive, relying on monitoring, intelligence, and post-listing takedowns. Overall, Malaysia's framework is substantively robust but insufficiently adapted to platform-based commerce, reflecting a misalignment between regulatory design and digital market realities (Mackey & Liang, 2013; Fairgrieve et al., 2024).

4.2 United States: Layered Regulatory Architecture

The United States approach towards pharmaceutical e-commerce is more integrated and layered. The FD&C Act establishes a baseline prohibition on the introduction of misbranded or unapproved medicines into interstate commerce. This law gives the Food and Drug Authority (FDA) the power to undertake administrative proceedings, issue civil injunctions, seize products, and initiate criminal proceedings, which establishes an effective foundation for product legality.

For controlled substances, the Ryan Haight Act provides some internet-specific protections. The law mandates the use of legitimate prescriptions issued in the context of legitimate medical practice and imposes registration requirements on online pharmacies that dispense controlled substances. This legislation minimises the risk of unauthorised sellers using digital prescribing systems by focusing on distribution channels directly.

The Drug Enforcement Administration (DEA) administer the enforcement of controlled substance regulations, including overseeing online pharmacy registration, compliance monitoring, and criminal investigations under federal drug control statutes. The Federal Trade Commission (FTC) regulates deceptive advertising, including misleading health claims in online marketplaces. The INFORM Act 2023 further strengthens the regulatory environment by requiring marketplaces to collect, verify, and disclose identity information of high-volume third-party sellers. Although Section 230 of the CDA provides general immunity for third-party content, it does not exempt platforms from federal criminal liability or sector-specific statutory obligations (Brannon & Holmes, 2024). In practice, many United States platforms also implement internal policies restricting prescription drug sales or requiring documentation from authorised sellers.

The combination of a baseline drug safety ban, Internet-wide restrictions on high-risk substances, transparency requirements in the marketplace, and coordination of the multi-agency enforcement creates structural friction against the sale of illicit pharmaceutical products. Although risks remain, the United States model demonstrates how sector-specific regulatory layering can reduce digital marketplace vulnerabilities (Fairgrieve et al., 2024).

5.0 Discussion

The comparative results show that the main regulatory issue in pharmaceutical e-commerce is not the lack of substantive drug control laws, but the incompatibility between the traditional pharmaceutical regulatory structure and the platform-mediated market architecture (Fairgrieve et al., 2024). Within e-marketplaces, platform architecture enables anonymity, algorithmic visibility, rapid relisting, and cross-border fulfilment, thereby undermining the effectiveness of traditional vendor-specific enforcement mechanisms (Liang & Mackey, 2009; Mackey & Nayyar, 2016).

The findings highlight that Malaysia's regulatory model remains predominantly disclosure-based rather than verification-based in digital environments. Consumer protection regulations require that information provided by sellers be visible, but they do not impose a statutory duty on platforms to verify that pharmaceutical licences have been issued before listing (Consumer Protection Act 1999; Consumer Protection (Electronic Trade Transactions) Regulations 2024). This structure produces reactive enforcement reliant on monitoring and takedown measures, placing significant burdens on regulators when seller identities are false, foreign, or easily recycled. While Malaysia maintains strong substantive drug controls, its digital gatekeeping remains comparatively limited.

In contrast, the United States adopts a layered regulatory framework that distributes responsibility across multiple institutions. The FD&C Act prohibits unlawful pharmaceutical distribution, while the Ryan Haight Act introduces internet-specific safeguards for controlled substances. The FTC regulates misleading claims, and the INFORM Act 2023 mandates identity verification for high-volume sellers. Although Section 230 of the CDA limits general intermediary liability, sector-specific statutes and transparency requirements reduce anonymity and enhance traceability (Brannon & Holmes, 2024). Together, these measures integrate substantive drug law with marketplace governance, creating pre-transaction safeguards in higher-risk categories (Fairgrieve et al., 2024).

Malaysia's enforcement approach remains largely post-harm, intervening after listings are published and consumers are exposed. By comparison, the United States model incorporates preventive friction through identity verification and internet-specific controls. In the pharmaceutical context, such preventive mechanisms are normatively justified given the clinical and counterfeit risks involved (World Health Organisation, 2026; Mackey & Nayyar, 2016). These findings support a calibrated gatekeeper theory of platform governance. Platforms are not passive conduits; they structure transactions, shape visibility and influence market trust (Fairgrieve et al., 2024). Their technological capacity positions them to manage systemic risks more effectively than post-hoc enforcement. A risk-based allocation of duties, therefore, justifies stronger verification and traceability requirements in high-risk sectors (Fairgrieve et al., 2024; Mackey & Liang, 2013).

Beyond the immediate regulatory comparison, these findings carry broader implications for institutional governance and digital market stability. Strengthening platform accountability in pharmaceutical e-commerce aligns with Sustainable Development Goal 16, which emphasises effective, accountable, and transparent institutions (United Nations, 2025). Clear verification and traceability standards enhance regulatory legitimacy and reinforce trust in the digital marketplace.

For Malaysia, reform should prioritise a shift from disclosure-based compliance to verification-based governance in pharmaceutical listings. Platforms should be required to authenticate seller authorisation for prescription and controlled medicines, ensure identity persistence to prevent account recycling, and maintain structured records to enhance traceability (Lim & Abdul Aziz, 2025). Greater integration between pharmacy regulation and digital trade governance would reduce institutional fragmentation and transform transparency mechanisms into preventive safeguards.

Although cross-border enforcement remains challenging (Lim & Abdul Aziz, 2025), improved verification and traceability can limit the scalability of foreign unauthorised sellers. The lesson from the United States is to adopt a sector-specific platform governance model

proportionate to pharmaceutical risk. Effective digital pharmaceutical regulation ultimately requires institutional recalibration aligned with platform-mediated commerce and public health protection.

Table 1: Structural Comparison of Pharmaceutical E-Commerce Governance

Regulatory Dimension	Malaysia	United States
Core Drug Control Law	PA 1952; SODA 1952; CDCR 1984	FD&C Act; Ryan Haight Act
Platform-Specific Duties	No explicit statutory verification duty for pharmaceutical listings	INFORM Act 2023 imposes identity verification for high-volume sellers
Intermediary Liability	Primarily governed by general e-commerce and consumer law	Section 230 of the CDA provides general immunity, limited by federal statutes
Verification vs Disclosure	Disclosure-based compliance (identity display requirements)	Verification-based transparency for high-volume sellers
Enforcement Model	Reactive; post-listing monitoring and takedown	Layered; combines drug law, FTC enforcement, and marketplace transparency
Traceability Mechanism	Limited statutory traceability obligation for platforms	Mandatory collection and verification of seller identity in certain contexts
Regulatory Coordination	Fragmented between pharmacy enforcement, communications regulator, customs	Multi-agency federal enforcement such as Drug Enforcement Administration (DEA), FDA and FTC.

(Source: Author's comparative analysis)

6.0 Conclusion & Recommendations

The digital transformation of pharmaceutical commerce presents regulatory challenges that extend beyond the traditional design of pharmacy legislation. This study demonstrates that Malaysia possesses a substantively robust pharmaceutical control framework grounded in registration, licensing, and advertising restrictions. However, these safeguards are significantly weakened in platform-mediated environments due to the absence of explicit platform-facing duties, limited seller traceability, and fragmented enforcement coordination. The comparative analysis with the United States shows that effective regulation of pharmaceutical e-commerce requires not only substantive drug control, but also preventive mechanisms embedded within platform governance.

Based on these findings, this study proposes several policy recommendations. First, statutory reform should introduce explicit platform verification duties for regulated pharmaceutical categories. E-commerce platforms should be required to verify seller authorisation and retain documentary proof before listing prescription or controlled medicines. Second, regulatory reforms should strengthen identity persistence to prevent repeated re-entry by unauthorised sellers. The mechanisms include enhanced identity verification, structured record-keeping, and traceability standards. Third, integration of pharmacy law with digital consumer protection frameworks to reduce fragmentation. Disclosure-based obligations should be complemented by verification-based mechanisms, particularly for high-risk health products. Fourth, enforcement coordination should be strengthened through clear data-sharing protocols among platforms, regulatory agencies, and enforcement bodies, especially to address cross-border transactions. These recommendations support a calibrated gatekeeper model in which platform responsibilities are proportionate to the risk profile of pharmaceutical products. Given the direct implications for patient safety, imposing intermediary duties is normatively justified as a matter of public health protection.

The doctrinal and comparative designs limit the findings of this study. It relies on statutory and secondary sources without incorporating empirical data such as stakeholder interviews or enforcement statistics. As a result, while the study identifies structural legal gaps and proposes normative reforms, it does not fully capture practical implementation challenges, including platform compliance behaviour, enforcement capacity, or industry response. Additionally, the focus on Malaysia and the United States may limit generalisability to other jurisdictions with different regulatory contexts. Future research should therefore incorporate empirical methods and broader comparative analysis, particularly within ASEAN, to evaluate the practical effectiveness and feasibility of proposed reforms.

In conclusion, Malaysia's regulatory framework remains strong in principle but requires structural adaptation to address platform-mediated risks. Strengthening verification, traceability, and regulatory coordination will enhance public health protection and ensure that digital innovation does not outpace regulatory accountability.

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Paper Contribution to Related Field of Study

This paper contributes to the growing field of digital governance and health law by providing a structured comparative analysis of platform liability in pharmaceutical e-commerce.

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