

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 has a comprehensive pharmaceutical legislation, but it's not adjusted to digital intermediaries. By comparison, the United States takes a complex regulatory approach that includes federal drug regulations as well as 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, 2025). The e-commerce platforms offer convenience, good prices, and easy access to the market. However, there are risks, especially with the spread of unregistered medicines, counterfeit drugs, and unauthorised sellers without professional supervision (Ahmed et al., 2022; Mackey & Nayyar, 2016). Recent enforcement actions demonstrate the magnitude of the digital pharmaceutical risks. During INTERPOL's Operation Pangea XVII (2025), authorities seized approximately USD 65 million in counterfeit pharmaceuticals, arrested 769 people worldwide, and disrupted 123 criminal networks (INTERPOL, 2025). In Malaysia, the authorities cleared approximately 7,000 online listings of pharmaceutical products (Lim & Yang, 2025). These statistics reveal that the unauthorised sale of pharmaceuticals online is a structural regulatory issue, not an isolated act of misconduct.

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Some of the statutes that govern pharmaceutical products in Malaysia include 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). These legislations are stringent in registration, licensing and advertising. However, they were developed within a conventional brick-and-mortar regulatory framework. Their extension to the digital market remains fragmented, particularly regarding platform accountability (Aditya Maulana Rizqi & Muhammad Ramli, 2024).

The United States has a different regulating structure. Pharmaceutical control is based on the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act) and the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act). Meanwhile, Section 230 of the Communications Decency Act of 1996 (CDA) caps platforms' liability for third-party content, while industry-specific laws create additional liability.

This study critically evaluates the adequacy of Malaysia's legal framework governing pharmaceutical sales through e-commerce platforms, focusing on platform accountability and seller traceability. It examines whether Malaysia's disclosure-based regulatory model is sufficient in platform-mediated markets or whether clearer statutory intermediary duties are required to safeguard public health. By comparing Malaysia with the United States, the study identifies structural regulatory gaps and proposes reforms suited to Malaysia's evolving digital governance environment. Accordingly, the study pursues three objectives: (i) to analyse Malaysia's current legal framework on pharmaceutical e-commerce; (ii) to examine the United States' regulatory approach to intermediary responsibility; and (iii) to propose calibrated reforms to strengthen Malaysia's digital pharmaceutical governance.

2.0 Literature Review

2.1 Pharmaceutical Online Risks.

The development of e-commerce has greatly changed how pharmaceutical products are accessed and distributed. Although online platforms offer convenience and a broader market, academic studies have consistently reported that online pharmaceutical sales are a highly risky area (Ahmed et al., 2022; Mackey & Nayyar, 2016). Some studies report that the digital space reduces sellers' entry barriers, thereby enabling unauthorised sellers to more easily sell counterfeit, substandard, or falsified medical products (Mackey and Liang, 2013; Liang and Mackey, 2009). Unlike traditional pharmacies, which have licensed pharmacists on-site and are subject to routine inspections, online sellers can hide their identities, operate across jurisdictions, and rapidly reappear under new accounts after enforcement actions.

A study by Alphonsoes et al. (2021) found that a significant percentage of prescription drugs on e-marketplaces have not been registered with the Drug Control Authority, indicating structural flaws in preventing unauthorised sales. This implies that the online platform could serve as an alternative to professional oversight and regulatory safeguards. The dangers were further highlighted during the COVID-19 pandemic, when unexpected demand for health-related items provided fertile ground for counterfeiters and opportunistic sellers (Ahmed et al., 2022; Mackey & Liang, 2013). The World Health Organisation has emphasised that online marketplaces facilitate the distribution of unsafe medical products without regulatory oversight (World Health Organisation, 2026). Pharmaceutical products directly affect patient health, and the improper use or ingestion of counterfeit products may lead to serious effects. Given these implications, researchers believe that regulatory strategies used for common consumer goods may be inappropriate for medicines, which require greater protection and control (Mackey & Liang, 2013).

2.2 Platform Governance and Intermediary Responsibility

Discussions about the governance of platforms are becoming more critical of the classical perspective of online intermediaries as passive providers of third-party content. The previous regulatory approaches were largely based on notice-and-takedown, only when notified of their existence. However, recent research found that major e-commerce platforms do much more than just host the content. They organise transactions, dictate visibility through algorithms, operate payment systems, and control sellers' access (Fairgrieve et al., 2024). In this regard, platforms actively shape organisational determinants of market behaviour.

This change has sparked broader debate about intermediaries' responsibilities. Legal scholars note that traditional product liability concepts were developed within the framework of physical shops and production facilities, and therefore it is quite challenging to apply them to online stores in a conceptually straightforward manner (Fairgrieve et al., 2024). Consequently, there has been a shift towards regulatory discourse models that focus on seller verification, transparency, and traceability mechanisms rather than basing regulatory discourse solely on post-hoc liability. Such changes in legislation, such as the INFORM Consumers Act 2023 (INFORM Act 2023) in the United States, are signs of this new focus on reducing anonymity in online trade (Brannon and Holmes, 2024).

In Malaysia, online transactions are regulated through general consumer protection and electronic commerce laws. The Electronic Commerce Act 2006 and the Consumer Protection Act 1999 support the rules of contractual fairness, electronic validity, and disclosure of the seller. A few studies found that the mechanisms of transparency and disclosure may be insufficient in industries with high health risks, as more robust oversight and verification measures are needed (Mackey and Liang, 2013; Fairgrieve et al., 2024). The distribution of responsibility is particularly sensitive in the context of pharmaceutical e-commerce because the injuries in question involve clinical safety and human well-being rather than simple monetary loss (Liang and Mackey, 2009). fact that injuries in question involve clinical safety and human well-being, but not the simple loss of money (Liang and Mackey, 2009).

Researchers note that although statutory pharmaceutical controls remain robust across jurisdictions such as Malaysia and the United States, transitioning them to platform-mediated settings poses ongoing legal and operational challenges (Mackey and Liang, 2013; Brannon and Holmes, 2024). The conflict between protecting intermediaries, their enforcement capabilities, and the public health threat

demonstrates that controlling digital marketplaces is complicated. There remains limited integration of pharmaceutical regulatory control with platform transparency obligations in a comparative context. This gap provides the foundation for the present study.

3.0 Methodology

This study adopts a qualitative doctrinal and comparative legal methodology. The doctrinal component systematically examines statutory provisions governing pharmaceutical regulation, advertising controls, consumer protection, and digital commerce in Malaysia and the United States. Primary sources include principal legislation, subsidiary regulations, and enforcement frameworks relevant to pharmaceutical distribution and intermediary accountability. Secondary sources, including academic scholarship, policy reports, and regulatory guidance, are used to contextualise and support doctrinal findings. Although this research is library-based and does not include stakeholder interviews or quantitative enforcement data, the breadth of statutory and scholarly material enables a structured, analytically grounded evaluation of digital pharmaceutical governance models.

The United States is selected as a comparator due to its layered federal regulatory architecture, particularly the interaction between substantive drug control law, intermediary immunity under section 230 of the CDA, and recent marketplace transparency reforms introduced by the INFORM Act 2023. This combination provides a mature example of how platform governance mechanisms may be integrated with sector-specific pharmaceutical controls. The comparison is therefore functionally appropriate for evaluating Malaysia's regulatory adaptation to digital pharmaceutical markets.

The comparative analysis follows a functional method, focusing on how each jurisdiction allocates regulatory responsibility within platform-mediated environments rather than merely contrasting statutory wording. This approach enables assessment of structural design, including seller verification mechanisms, traceability standards, intermediary liability boundaries, and enforcement coordination. A functional comparison is particularly suitable when the objective is regulatory reform, as it identifies transferable institutional mechanisms rather than superficial doctrinal similarities.

4.0 Findings

4.1 Malaysia: Substantive Strength with Digital Gaps

The pharmaceutical products regulatory system in Malaysia is substantively and firmly grounded in protecting public health. PA 1952, SODA 1952, and CDCR 1984 have stringent registration conditions, licensing regulations, and advertising prohibitions. Pharmaceutical products must be registered with the Drug Control Authority, and prescription-only medicines must be dispensed only with a prescription and supplied by authorised professionals. These legislative protection mechanisms reflect an aggressive, regulatory-process-based philosophy that prioritises product safety, efficacy, and professional oversight to safeguard consumers from illicit or ineffective medical products (Zuryani et al., 2021).

This framework works well in traditional brick-and-mortar environments. Pharmacy premises with licensed pharmacists are regulated through routine inspections by the authority, and enforcement actions can be pursued, such as seizures and prosecutions. However, the shift in pharmaceutical product sales to e-commerce reveals structural weaknesses in the regulatory framework. E-commerce marketplaces enable rapid seller registration, anonymous accounts, and cross-border transactions, which complicate regulation (Lim & Abdul Aziz, 2025; Mackey & Nayyar, 2016). While it is clear under Malaysian law that the sale of prescription drugs and unregistered pharmaceutical products is illegal, the statutory provisions do not explicitly impose an affirmative obligation on e-commerce sites to ensure that sellers offer legitimate pharmaceutical products.

This absence of explicit platform-facing accountability creates a weakness in enforcement. The distribution of regulators involves multiple agencies, such as pharmaceutical enforcement agencies, communications regulators, and customs agencies, which can lead to fragmentation and delays in digital investigations (Lim & Abdul Aziz, 2025). Moreover, international transactions involving foreign sellers or fulfilment centres create jurisdictional boundaries that delay enforcement responses and make evidence collection more challenging (Lim & Abdul Aziz, 2025).

Despite consumer protection laws requiring sellers to disclose some identity and transactional details, these laws are more about disclosure than verification (Consumer Protection Act 1999; Consumer Protection (Electronic Trade Transactions) Regulations 2024). A platform must disclose information about sellers, but it is not a statutory requirement to verify a pharmaceutical licence before listing. Therefore, the enforcement mechanism tends to be reactive and complaint-based, based on the monitoring, intelligence profiling, and post-listing takedown requests. Overall, Malaysia has extensive substantive pharmaceutical regulations but relatively fewer in the digital systems. The regulatory framework is not well-adapted to the technological landscape of platform-based trading (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 in its regulatory approach. The FD&C Act provides a baseline prohibition against the introduction of misbranded or unapproved medicines in interstate commerce. This law gives the Food and Drug (FDA) Authority the power to undertake administrative proceedings, civil injunctions, product confiscations, and criminal proceedings, which establishes an effective foundation of product legality.

In the case of controlled substances, the Ryan Haight Act provides some internet-specific protections. The law mandates the use of legitimate prescriptions that are issued in the context of legitimate medical practice and gives registration requirements to the online

pharmacies that dispense controlled substances. This legislation minimises the chance of those operating unauthorised sellers using digital prescribing systems by focusing on distribution channels directly.

Enforcement of controlled substance regulation is administered by the Drug Enforcement Administration (DEA), which oversees 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 rather 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 U.S. 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 is not to replicate U.S. intermediary immunity doctrines, but 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 has demonstrated that Malaysia possesses a substantively robust pharmaceutical control framework grounded in registration requirements, licensing standards, and advertising restrictions. However, the effectiveness of these safeguards is significantly weakened in platform-mediated environments due to limited statutory duties imposed on platforms, weak seller traceability mechanisms, and fragmented digital enforcement coordination. The comparative analysis with the United States shows that effective regulation of pharmaceutical e-commerce requires more than substantive drug control provisions alone.

Based on these findings, several policy recommendations are proposed for Malaysia. First, statutory reform should establish explicit platform verification duties for regulated pharmaceutical categories. E-commerce platforms should be required to verify seller authorisation and retain documentary proof of licensing prior to listing prescription or controlled medicines. Second, regulatory changes should strengthen seller identity persistence to prevent rapid account recycling. Enhanced identity verification, structured record-keeping obligations, and traceability standards would improve enforcement efficiency and reduce investigative burdens on regulatory authorities. Third, pharmacy law and digital consumer protection frameworks should be harmonised to minimise institutional fragmentation. Disclosure-based obligations must be complemented by verification-based compliance mechanisms for regulated health products, transforming transparency requirements into preventive governance tools. Fourth, enforcement coordination mechanisms should be strengthened to address cross-border pharmaceutical transactions. Clear protocols for data sharing among platforms, regulatory agencies, and enforcement bodies would enhance evidentiary preservation and improve responsiveness in digital investigations. Importantly, these recommendations do not advocate universal pre-screening of all online content. Rather, they support a calibrated gatekeeper model in which platform duties are proportionate to the risk profile of pharmaceutical products. Given the clinical risks and exposure to counterfeit products associated with unauthorised pharmaceutical sales, intermediary responsibility is normatively justified as a matter of public health protection.

This study is doctrinal and comparative in nature and does not incorporate empirical interviews or quantitative enforcement data. While the analysis provides a structured legal evaluation, implementation challenges in practice may vary across institutional contexts. Future research may therefore explore empirical enforcement dynamics, platform compliance costs, and comparative ASEAN regulatory models to assess the operational impact of proposed reforms.

In conclusion, Malaysia's pharmaceutical regulatory framework remains strong in principle but requires structural adaptation to address the realities of platform-mediated trade. Clarifying platform duties, strengthening traceability mechanisms, and harmonising regulatory regimes will enhance consumer protection and reinforce public health governance in the digital marketplace. Such reforms align with broader goals of effective institutional governance and sustainable digital commerce, ensuring that technological 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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