IARJSET ISSN (O) 2393-8021, ISSN (P) 2394-1588

International Advanced Research Journal in Science, Engineering and Technology

Impact Factor 8.311 ⁜ Peer-reviewed & Refereed journal ⁜ Vol. 12, Issue 12, December 2025

DOI: 10.17148/IARJSET.2025.121209

Navigating the Digital Dispensary: A Critical Analysis of Regulatory, Operational, and Ethical Challenges of E-Pharmacy in India

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Abstract: The pharmaceutical sector in India is undergoing a paradigm shift, driven by rapid digitization and increasing internet penetration. E-pharmacies online platforms facilitating the sale of medicines have emerged as a significant disruptor, promising accessibility, affordability, and convenience. However, this burgeoning sector operates within a complex ecosystem fraught with challenges. This paper explores the multifaceted hurdles facing e-pharmacies in India, categorized into regulatory ambiguity, operational logistics, patient safety concerns, and the socio-economic conflict with traditional brick-and-mortar retailers. Through an analysis of the current legal framework and market dynamics, this study argues that while e-pharmacies hold immense potential for public health, a robust and clear regulatory mechanism is a prerequisite for sustainable growth.

1.INTRODUCTION

The intersection of technology and healthcare has revolutionized service delivery in India. Following the success of e-commerce in retail and food sectors, the pharmaceutical industry has witnessed the meteoric rise of "e-pharmacies." Estimates suggest that the Indian e-pharmacy market is projected to grow at a robust compound annual growth rate (CAGR), fueled by the post-pandemic shift in consumer behavior and the "Digital India" initiative (FICCI, 2022). However, unlike buying clothes or electronics, the online sale of drugs involves critical health implications. The transition has not been smooth; it is marred by a "legal vacuum" where technology has outpaced legislation. The primary challenge lies in reconciling the archaic *Drugs and Cosmetics Act, 1940* with modern digital commerce (Iyengar & Gupta, 2020). This paper examines the challenges of e-pharmacy in India, focusing on the regulatory, operational, and ethical bottlenecks that impede the sector's maturity.

2. PURPOSE OF THE RESEARCH

The primary purpose of this research is to critically evaluate the sustainability of the e-pharmacy model in India amidst a volatile regulatory and operational landscape. While the sector promises to democratize healthcare access, its growth is currently outpacing the legislative framework, creating significant public health and economic risks; evaluating Regulatory vacuum, Assessing Patient Safety and Market dynamics.

3. METHODOLOGY

To achieve the objectives outlined above, this study adopts a qualitative, secondary research methodology (Desk Research), supported by a systematic review of legal statutes, market reports, and academic literature. Data was aggregated from three primary streams: Analysis of the *Draft E-Pharmacy Rules (2018)*, notifications from the Central Drugs Standard Control Organization (CDSCO), and judgments from the Delhi and Madras High Courts (2018–2025), Financial performance data and sector projections were sourced from industry whitepapers by FICCI, EY, and IMARC Group (2022–2025).

The collected data was analyzed using a Content Analysis approach. Information was coded into four distinct themes: (1) Regulatory Compliance, (2) Logistics & Operations, (3) Economic Impact, and (4) Ethical Concerns. This allowed for the triangulation of findings, where industry claims of "efficiency" were cross-verified against academic findings on "safety risks" to present a balanced view.

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4. LITERATURE REVIEW

The existing body of literature on Indian e-pharmacies reveals a sharp divide between the technological optimism of market analysts and the safety concerns of public health experts.

4.1: The Regulatory "Grey Zone" Scholars universally agree that the current legal framework is outdated. Iyengar and Gupta (2020) argue that the *Drugs and Cosmetics Act, 1940* is "territorial" by design, linking a license to a specific physical premise, a concept incompatible with the borderless nature of e-commerce. This view is supported by recent legal analyses of the *Zaheer Ahmed v. Union of India* (2018) case, where the Delhi High Court highlighted the inability of current laws to prevent the online sale of prohibited drugs (Malhotra, 2021). More recently, Haripriya et al. (2025) emphasized that without the notification of the Draft Rules 2018, e-pharmacies continue to operate under a "safe harbor" provision of the IT Act, which ostensibly shields them from liability for vendor misconduct a loophole that endangers patient safety.

4.2: Patient Safety and Antimicrobial Resistance A significant portion of the literature focuses on the public health implications of e-pharmacies. A pivotal study by Chaudhary et al. (2021) found that e-pharmacies could inadvertently fuel India's antimicrobial resistance (AMR) crisis. Their research indicated that while major platforms have tightened prescription verification, smaller "rogue" sites still process orders for antibiotics with invalid or reused prescriptions. Furthermore, Satheesh et al. (2025) conducted a compliance check of e-pharmacies serving India and Kenya, revealing that while Indian sites showed better adherence to digital payments, significant gaps remained in the verification of Schedule H drugs compared to global best practices.

4.3: Operational Models and Economic Viability From a business perspective, the literature highlights the struggle for profitability. The "Marketplace" model, while asset-light, is criticized for its lack of quality control. Research by the Competition Commission of India (CCI) suggests that deep discounting by e-pharmacies is not merely an efficiency gain but a "customer acquisition cost" funded by venture capital, which distorts the market (CCI, 2018). Recent financial analyses of FY24 performance indicate a shift: companies like Tata 1mg are moving toward an "Inventory-led" model to ensure better margins and quality control, validating earlier theoretical predictions by Mishra (2024) that hybrid models would eventually dominate the Indian landscape.

4.4: The Urban-Rural Divide While e-pharmacies tout accessibility as their main benefit, Sharma and Rao (2022) counter this narrative with empirical data showing that 70% of e-pharmacy gross merchandise value (GMV) comes from top-tier metros. Their study highlights that the "digital divide" and poor logistical infrastructure in rural India limit the benefits of e-pharmacies to the urban affluent, thereby failing to address the core issue of healthcare access in remote areas

5. RECENT DEVELOPMENTS & MARKET ANALYSIS

The period between 2024 and early 2025 marked a phase of "correction and consolidation" for the Indian e-pharmacy sector. While the market continues to expand, major players have shifted focus from aggressive customer acquisition to financial sustainability, largely due to a funding winter and intensified regulatory scrutiny. Despite regulatory headwinds, the sector shows robust growth potential, driven by the increasing digital penetration in Tier-2 and Tier-3 cities. However, valuation corrections have been severe.

Table-1: Indian E-Pharmacy Market Statistics & Projections

Metric	Statistic / Projection	Source
Market Size (2024)	USD 3.18 Billion	IMARC Group (2025)
Projected Market (2033)	USD 12.71 Billion	IMARC Group (2025)
CAGR (2025–2033)	16.65%	IMARC Group (2025)
Dominant Segment	Prescription Medicines (79% share)	Grand View Research (2024)
Key Growth Driver	Rising chronic disease prevalence & telemedicine integration	FICCI & EY (2024)

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6. Financial Performance of Key Players (FY24)

The financial year 2023-24 (FY24) saw a distinct divergence in strategy between market leaders. Tata 1mg focused on improving unit economics, significantly reducing losses. In contrast, PharmEasy faced a valuation markdown and shrinking revenue as it cut costs to survive a liquidity crunch.

Table-2: Comparative Financial Performance of Leading E-pharmacies (FY24)

Metric	Tata 1mg	PharmEasy (API Holdings)
Operating Revenue	₹1,968 Cr (↑ 21% YoY)	₹5,664 Cr (↓ 15% YoY)
Net Loss	₹313 Cr (↓ 75% YoY)	₹2,533 Cr (↓ 50% YoY)
Primary Strategy	Operational efficiency & reduced burn	Debt restructuring & survival
Valuation Trend	Stable (Backed by Tata Group)	Downward (90% devaluation)

Source: Entrackr, 2024; Financial Express, 2024

To understand the disparity in financial health between major players like Tata 1mg and PharmEasy in FY24-25, it is essential to analyze the structural differences in their operational models. In the Indian context, FDI (Foreign Direct Investment) regulations prohibit e-commerce entities from holding inventory for direct B2C sales, forcing companies to adopt creative structure.

Table-3: Comparison of Business Models

Feature	Inventory-Led / Hybrid Model	Marketplace
Core Operation	The platform has tight control over the supply chain. While they may technically sell through licensed sellers, they often own the distribution centers (warehouses) and stock.	The platform acts strictly as a technology intermediary, connecting the patient app to local offline pharmacies (vendors) who fulfill the order.
Revenue Source	Higher margins derived from the difference between wholesale procurement cost and retail price.	Low margins derived solely from commissions (take-rate) charged to the local pharmacy for generating the lead.
Quality Control	High. Since the stock moves through platform-controlled warehouses, checking for counterfeits and maintaining cold chain is easier.	Variable. Reliance on third-party local chemists makes it difficult to guarantee that a specific vendor maintains proper storage conditions.
Delivery Speed	Slower (Standard Delivery). Ships from central hubs, usually taking 24-48 hours.	Faster (Hyperlocal). Can deliver in hours since the fulfillment is done by a nearby shop.
Capital Expenditure	High. Requires heavy investment in warehousing, inventory, and logistics fleet.	Low (Asset Light). Leverages the existing infrastructure of local chemists.
Regulatory Risk	Moderate. Easier to prove compliance with storage norms, but faces scrutiny over "inventory ownership" rules for FDI.	High. Harder to verify if every partner vendor is strictly following prescription verification laws.

7. CHALLENGES OF E-PHARMACIES

7.1 The Regulatory Quagmire:

The most significant impediment to the e-pharmacy sector in India is the lack of a concrete legal framework. Currently, the sale of medicines is governed by the *Drugs and Cosmetics Act, 1940* and the *Drugs and Cosmetics Rules, 1945*. These laws were drafted long before the internet existed and mandate that medicines be sold only from a licensed premise under the supervision of a registered pharmacist (Create, 2019).

E-pharmacies typically operate under two models: the inventory model (owning the stock) and the marketplace model (connecting buyers with registered vendors). While the *Draft E-Pharmacy Rules, 2018* attempted to legitimize and regulate these platforms, they have yet to be notified as law (Government of India, 2018). This delay has resulted in a regulatory grey area. "The absence of specific legislation has led to conflicting judicial interpretations, with various High Courts issuing stays on e-pharmacy operations, citing risks to public health" (Malhotra, 2021). Without clear guidelines on jurisdiction, licensing, and liability, e-pharmacy platforms face constant legal uncertainty, deterring investment and complicating compliance.

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7.2 Operational Barriers: Beyond the courts, e-pharmacies face immense operational challenges inherent to India's geography and infrastructure

7.3 Cold Chain Maintenance: India is a tropical country with extreme temperature variations. Many distinct classes of drugs, including insulin, vaccines, and certain biologics, require strict temperature control (2°C to 8°C) throughout the supply chain. Maintaining this "cold chain" during last-mile delivery, especially in Tier-2 and Tier-3 cities where power outages are common, is a logistical nightmare and a significant cost driver (Logistics Bureau, 2023). A breach in the cold chain renders these medicines ineffective or harmful, posing a direct liability to the platform.

7.4 Last-mile Connectivity: While e-pharmacies promise accessibility to rural areas, the reality is often limited to urban metros. The cost of logistics in rural India is high due to poor road infrastructure and scattered population density. Consequently, the "access" argument often touted by proponents of e-pharmacy currently applies largely to the urban middle class, exacerbating the urban-rural healthcare divide rather than bridging it (Sharma & Rao, 2022).

7.5 Patient Safety & Ethical Concerns: The virtualization of the pharmacist-patient relationship introduces several safety risks that traditional pharmacies are better equipped to handle.

7.6 Prescription Validation: The primary ethical concern is the validation of digital prescriptions. In a physical store, a pharmacist can visually verify the authenticity of a script. Online, patients may upload old, reused, or forged prescriptions to procure restricted medicines. There is a tangible risk of e-pharmacies becoming conduits for the abuse of habit-forming drugs, sedatives, and antibiotics, contributing to the growing crisis of antimicrobial resistance (Chaudhary et al., 2021).

7.7. Counterfeit Drugs: The World Health Organization (WHO) estimates that a significant percentage of drugs sold online globally are counterfeit. In an online marketplace model, where the platform aggregates multiple third-party sellers, quality control becomes difficult. If a vendor ships a spurious drug, the traceability and liability of the platform versus the vendor remain contentious issues (WHO, 2020).

7.8 Data Privacy: E-pharmacies collect vast amounts of sensitive personal health data (PHI), including medical history and prescription patterns. In the absence of the full implementation of the *Digital Personal Data Protection Act*, there are fears regarding how this data is stored, shared, or monetized for targeted advertising by pharmaceutical companies (Datta, 2023)**.** The rise of e-pharmacy has triggered fierce opposition from the All-India Organization of Chemists and Druggists (AIOCD), which represents over 800,000 brick-and-mortar pharmacists**.** The AIOCD argues that e-pharmacies engage in "predatory pricing" offering deep discounts (up to 20-30%) funded by venture capital to acquire customers, which traditional family-owned pharmacies cannot match (AIOCD, 2022).

8. CONCLUSION

E-pharmacies in India stand at a critical juncture. They offer a technological solution to the issues of accessibility and convenience, yet they are hamstrung by a regulatory framework from the pre-digital era. The challenges are not merely legal but extend to the physical realities of logistics and the ethical imperatives of patient safety. For the sector to thrive sustainably, the Government of India must expedite the notification of the E-Pharmacy Rules. These rules must mandate strict e-prescription verification systems, define data privacy standards, and ensure a level playing field regarding pricing to protect small retailers. Only through a "phygital" approach blending digital efficiency with the safety protocols of physical pharmacy can the full potential of e-pharmacy be realized in India.

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