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COMBATING ILLEGAL ONLINE PHARMACIES: REGULATORY STRATEGIES FOR THE INDIAN MARKET

AUTHORED BY - JEEVA THOMAS MANNANAL

ABSTRACT

With the advent of e-pharmacies supported by technological development and wider availability of the internet, healthcare service and medications consumption pattern has been transformed. These online services provide unmatched ease of access, cost savings, and increased availability of essential medications, making them particularly beneficial for people living in remote, rural, or underserved areas. The rise of e-pharmacies has made it so much easier for patients to order medications right from home, often at lower prices and with a wider selection. This really boosts access to e-healthcare and how well it works overall. Plus, these platforms typically include helpful features like automatic prescription fills, refill reminders, and access to medication history, all of which improve the user experience. Yet, incredible growth of e-pharmacies has imposed a variety of challenges. Problems related to drug authenticity and quality, risk to patient safety and safeguarding of personal health information has become a serious issue. Furthermore, the digitality of e-pharmacies creates the potential for misuse of prescription drugs, thereby increasing concerns for drug abuse and the distribution of counterfeit or sub-standard drugs. The lack of a robust regulatory supervision facilitates the escalation of these risks leaving the consumer susceptible to fraudulent cases, substandard goods and breaches of privacy. Despite the potential to increase the accessibility and cost-effectiveness of medical care, e-pharmacies are rapidly spreading and are a potential public health and safety liability. To develop optimal use of the potential benefits of this new frontier and to address the perspectives and limitations of this new frontier, a robust regulatory apparatus is necessary. Through regulation that avoids excessive innovation, e-pharmacies in India can be ensured to improve the scene of healthcare, enhance the protection of consumer rights and maintain the standards of quality of the best possible safety.

Keywords: E-pharmacies, access to medication history, privacy, consumer rights, drug abuse, healthcare accessibility

INTRODUCTION

The e-pharmaceutical industry shows promise for growth and has caught the eye of investors, but legal battles plague it. This creates doubt for investors, as the government hasn't made clear if FDI is allowed or set up clear rules or licensing. This lack of direction hurts the industry and makes it clear we need proper regulations fast. While they offer many benefits, the rise of e-pharmacies in the country has brought up some real worries. At the moment, online pharmacies operate in a bit of a legal gray zone since there aren't any clear regulations governing them. They still need to comply with the old Drugs and Cosmetics Act from 1940, along with the Drugs and Cosmetic Rules established in 1945. To address this issue, the Ministry of Health and Family Welfare introduced the Draft Rules on Sale of Drugs by E-Pharmacy in 2018, aiming to revise the Act and create guidelines specifically for e-pharmacies. This move came about after encouragement from the Delhi and Madras High Courts. Without specific rules for e-pharmacies, they've had to stick to rules made for regular pharmacies, which don't work well to oversee how they run and do business. E-pharmacies have caused heated arguments and strong resistance from traditional pharmacies and doctors. They question the legality of these online businesses how they fit under Indian law, and worry about fake prescriptions that could put patients at risk. People also fear the wrong use of drugs that can lead to addiction. E-Pharmacy is a new field that got popular thanks to business owners who wanted to give good cheap healthcare to everyone in India. People's choice for E-pharmacy went up from 23% in 2013 to about 59% in 2018. A lot of talk has been about the need for a system to give licenses and decide who will make rules for e-pharmacies. The Drugs and Cosmetics Act of 1940 is the central law that controls how medicines are sold and given out in India. This law was made for regular pharmacies, not online ones. The Act says you need a license to sell drugs, and to get this license, you must have a real place to keep the drugs. The Act also says a licensed pharmacist must be there when selling prescription drugs and some other drugs that need watching. This means online pharmacies must follow these rules too, including having a real storage place, and can't work in India without one. There aren't any set rules for online pharmacies yet, but some Draft Rules are waiting to be approved. According to these rules, anyone intending to sell drugs through a website or an internet-based model must obtain a registration certificate from the licensing authority by submitting an application via Form 18AA. Exceptionally, e-pharmacy will only get a certificate from the drug control office if the pharmacy is controlled in a way that makes it operate in India by the web portal; whereas a registered pharmacist should be the manager of the pharmacy; and, the pharmacy should not offer for sale drugs classified under the Narcotic and Psychotropic Substances Act, 1985, or

Schedule X of the Rules.

BENEFITS OF E- PHARMACIES

The online pharmacy provides several benefits that have changed the way the people get medications, bringing the health care closer, and more efficient and cost-friendly. A key benefit of e-pharmacies is their convenience. They allow people to order medications right from home, eliminating the need to visit a local pharmacy in person. This is particularly beneficial for individuals with disabilities, chronic illnesses, or those living in rural areas who might struggle to access traditional pharmacies. The majority of e-pharmacies are open 24/7, which means that there is access to drugs every time. Affordability is a major plus with e-pharmacies. They usually offer competitive prices and discounts, giving customers the chance to compare costs across different sites to snag the best deals. In fact, many online pharmacies sell medications at lower prices than traditional ones, especially when it comes to generic alternatives or bulk purchases. Another significant benefit is the wide range of medications available; e-pharmacies often stock a more extensive selection, including rare or specialized drugs that might not be found in local shops. This can be a real lifesaver for those who need hard-to-find medications for particular health issues. Additionally, e-pharmacies provide better privacy and discretion. Ordering medications online, especially for sensitive health matters, allows patients to keep their information confidential. Plus, many of these pharmacies offer helpful automated features like refill reminders, prescription management, and easy access to past orders, making it easier for patients to stick to their medication schedules. In summary, e-pharmacies enhance access to medications, save money, and improve medication management. They really are a modern solution for many patients, making healthcare more accessible and tailored to individual needs. However, it's crucial to stick with licensed and regulated platforms to ensure safety and quality.

COMPETITIVE ADVANTAGES IN E-PHARMACY MARKET

E-pharmacies tend to adopt broad strategies instead of narrowing their focus to specific segments. Their goal is to cater to all consumers who need medications, rather than just a select few. Moreover, these online pharmacies place a higher emphasis on keeping costs low rather than building a unique brand, as most medications are largely similar, and generic options are readily available. The products found in e-pharmacies aren't particularly special; you can find the same items in traditional pharmacies as well. In India, there are legal restrictions that restrict e-pharmacies from selling certain types of drugs. Still, the convenience of accessing these

services online helps them stand out from physical pharmacies, giving e-pharmacies a competitive edge through both cost savings and unique service offerings. To start with, online pharmacies typically rely on either an inventory-based model or a platform-based model, which allows them to cut operational costs substantially. This approach helps them avoid or significantly reduce expenses associated with running a physical store, such as rent, hiring qualified staff, purchasing equipment, and local marketing efforts. Additionally, the efficiency of their online systems speeds up transaction times for customers, further trimming costs. Next, e-pharmacies generally operate on a much larger scale than local pharmacies. They frequently attract venture capital and funding, which enables them to market their services widely and offer competitive pricing—this is a common trend in e-commerce. Such funding also allows them to roll out promotional offers like free delivery or discounted medical tests. Furthermore, the marketing efforts of online pharmacies are designed to appeal to a vast customer base that extends beyond geographical limits. Throughout the COVID-19 pandemic, more people turned to online ordering as it eliminated the need to go to physical stores, wait for service, or travel to find medications. This broad reach and the ability to provide home delivery with shorter wait times have proven to be advantageous. Also, e-pharmacies benefit from economies of scale owing to their large customer base, which provides them with a significant advantage over traditional brick-and-mortar stores. They often provide extra services, such as reliable diagnostic options and detailed information on medications—including usage instructions, side effects, and precautions—usually at no cost to help educate their customers. They even offer online consultations with registered doctors for just a minimal fee. Finally, e-pharmacies can help customers save money on medical expenses by providing generic medications, which are generally more affordable than brand-name drugs found in conventional pharmacies.¹

REGULATION OF E-PHARMACIES

In India, the manufacture, sale, and distribution of pharmaceutical products are governed by several laws, such as the Drugs and Cosmetics Act of 1940, the Drugs and Cosmetics Rules established in 1945, the Pharmacy Act from 1948, the Pharmacy Practice Regulations of 2015, and the Drugs and Magic Remedies (Objectionable Advertisement) Act of 1954. A major point of discussion is whether these regulations extend to e-pharmacies. Although the Drugs and Cosmetics Act and its corresponding rules don't explicitly mention online medicine sales, in

¹ Ritika Jain, Competitive Advantages and Competition Issues: Analysis of E-Pharmacy Market in India, 4 INT'L J.L. MGMT. & HUMAN. 962 (2021).

2015, the Office of Drugs Controller made it clear that there's no difference in how conventional and online drug sales are treated under the DCA and DCR. This means e-pharmacies need to follow these rules just like traditional pharmacies. In 2016, the Federation of Indian Chambers of Commerce and Industry (FICCI) introduced a Self-Regulation Code of Conduct aimed at e-pharmacies, but it doesn't hold any legal power. Even with the Drugs Controller's stance that allows e-pharmacies to operate under the Drugs and Cosmetics Act, the courts saw things differently. For instance, in 2018, the Madras High Court decided that online medicine sales couldn't proceed until the Drugs and Cosmetics (Amendment Rules) of 2018 were formally announced. That same year, a case was brought before the Delhi High Court in *Zaheer Ahmed v. Union of India*², which sought to limit the online sale of drugs through e-pharmacies. The Court issued a temporary order banning the online sale of unlicensed medications. A similar situation occurred with the *Tamil Nadu Chemists and Druggists Association v. Union of India*³, where a Single Judge ordered online pharmacies to stop selling drugs until the proposed "Draft E-pharmacy Rules, 2018" became official. E-pharmacies that operate on an inventory model appealed this decision, arguing that they were legally compliant since they possessed valid wholesale and retail licenses and their medications were dispensed by licensed pharmacists. On the other hand, marketplace-based e-pharmacies contended that they simply acted as digital platforms linking customers with authorized pharmacies, and were abiding by the Information Technology Act of 2000. The Division Bench ultimately put a hold on the Single Judge's order, highlighting that it was the responsibility of enforcement agencies under the Drugs and Cosmetics Act to handle violations, and that an abrupt ban on online sales could adversely affect patients who rely on these services. On March 15, 2023, the Central Government let the Delhi High Court know that it was in the process of drafting guidelines to regulate e-pharmacies and asked for more time to get this done. Then, on May 22, 2023, the Delhi High Court instructed the government to provide a report in six weeks about the feedback from stakeholders concerning the draft e-pharmacy rules. The next hearing on this issue is set for August 28, 2023. This situation highlights the absence of thorough regulations concerning e-pharmacies in India. Right now, licensed e-pharmacies are operating by exploiting the vague lines between online and offline pharmacies under the DCA. Some e-pharmacies argue they're just marketplaces, linking registered pharmacies with customers. They see themselves as intermediaries under the Information Technology Act, 2000 (IT Act), claiming they don't need a license for selling drugs since the actual dispensing of

² *Zaheer Ahmed v Union of India W.P. (C) 11711/2018*

³ *Tamil Nadu Chemist and Druggist Association v Union of India 2019 (1) CTC 548*

medicines occurs at physical pharmacies. While e-pharmacies fall under the purview of the Drugs and Cosmetics Act and the Drugs and Cosmetics Rules, it's crucial to note that these laws were formulated before the internet became prevalent and mainly focus on drug sales through brick-and-mortar stores. They were created with the risks and challenges of traditional pharmacies in mind, not those unique to online operations. According to the Pharmacy Act 1948 and the 5Drugs and Cosmetics Rules 1945, only registered pharmacists are allowed to dispense medications based on a prescription from a doctor. With e-pharmacies, there's a significant challenge in ensuring that drugs are dispensed by a registered pharmacist. Moreover, the Pharmacy Practice Regulations, 2015, require pharmacists to advise patients on how to use medications properly, any potential side effects, and other essential information. This is a requirement that e-pharmacies might not completely fulfill. One possible way to tackle this issue could be to restrict the online sale of medicines to over-the-counter items, which don't need a pharmacist for dispensing.⁴

DRAFT RULES ON REGULATION OF E-PHARMACIES 2018

The draft regulations introduce the concept of E-pharmacy as the online distribution or sale of medications through a website or any electronic platform. Only E-pharmacies that have been approved by the Central Licensing Authority are allowed to function. While these new rules signify progress, they fall short of addressing all the challenges associated with operating online pharmacies. Governments around the world are finding it difficult to eliminate illegal online pharmacies, which often offer unsafe or prohibited drugs without proper prescriptions and in dangerous quantities. Identifying these illegal websites and holding them accountable is challenging due to their secretive nature. The draft regulations primarily focus on regular inspections of the registered pharmacies and include the possibility of revoking licenses for those that fail to follow the guidelines. However, they fall short of including strategies for tackling illegitimate websites or bringing them to justice. To enhance the situation, policymakers should consider establishing a dedicated agency or giving more powers to the Drugs Controller General of India. This would help in identifying and blocking illegal sites that sell medicines while also raising awareness among consumers. Moreover, the draft rules should outline penalties or legal consequences to discourage illegal pharmacy operations. Many customers are drawn in by illegal pharmacies that sell banned medications at cheaper rates and in larger quantities. To tackle this issue, the government should collaborate with

⁴ Manupatra, Aditee Dash, Available at: <https://articles.manupatra.com/article-details/Need-for-regulation-in-the-E-Pharmaceutical-sector-in-India> (Accessed: 11 September 2024).

domain registration companies and search engines to identify and block these problem sites, which would help reduce consumer access. It's also crucial to penalize web platforms that host these illegal sites and to encourage internet service providers to assist in limiting access; these could be effective ways to combat rogue pharmacies. Another major challenge lies in the presence of online pharmacies based overseas. The proposed rules require that all patient-related information remains within India. This could impact consumers in a couple of significant ways: first, reduced competition from international pharmacies might limit access to high-quality medications; or second, the added costs for necessary infrastructure could lead to higher prices. Hence, it's crucial to have suitable regulations that ensure these foreign pharmacies adhere to national laws in the best interest of consumers. Many countries find it difficult to regulate and hold these foreign online pharmacies accountable. To tackle this effectively, international cooperation with bodies like the World Health Organization and the World Trade Organization is vital to protect individuals from illegal online pharmacies operating across borders.⁵

INTERNATIONAL AND INDIAN CONTEXT IN E-PHARMACY

India's e-pharmacy sector is still quite young, having kicked off in the early 2010s with the emergence of startups like Netmeds, 1mg, PharmEasy, Medlife, and Apollo Pharmacy. This growth has been fueled by greater internet access and a rising demand for convenient healthcare options. However, the journey hasn't been without hurdles. In 2018, the Indian government rolled out regulations that mandated e-pharmacies to get licenses and adhere to standards for prescription verification and quality control. While some companies initially pushed back against these rules, things became clearer in 2020 when the government refined the regulatory landscape, providing more stability for the industry. Even with the challenges, India's e-pharmacy scene keeps expanding. On a global scale, regulations for e-pharmacies differ from one country to another, but many align with guidelines from authorities like the World Health Organization (WHO) and the International Pharmaceutical Federation (FIP). These guidelines address key areas, including licensing, product validation, and patient safety. Take the U.S., for instance—here, e-pharmacies need to be licensed by the state they operate in, alongside following rules for prescription validation and patient confidentiality. In India, the framework governing e-pharmacies falls under the Drugs and Cosmetics Act (1940) and the Pharmacy Act

⁵Musyuni, P. (2020) *Regulation of e-pharmacies in India*, Lexology. Available at: <https://www.lexology.com/library/detail.aspx?g=be7476c9-6d91-41a4-bc20-6fe78637bc22> (Accessed: 13 September 2024).

(1948). With the 2018 regulations, there were new requirements for e-pharmacies to secure licenses and observe guidelines regarding prescription checks, quality assurance, and data safety. E-pharmacies in India need to get a license from either the Central Drugs Standard Control Organization (CDSCO) or a State Drugs Control Organization (SDCO) to operate legally. They have to make sure that prescription medications are only dispensed with a valid prescription from a registered medical professional. On top of that, e-pharmacies must ensure that all the medicines sold on their platform are genuine and of good quality, while keeping thorough records of every transaction. It's also essential for them to comply with India's data protection and privacy laws, including the upcoming Personal Data Protection Bill. Lastly, e-pharmacies need to guarantee that all medicines are properly labeled, packaged, and shipped to ensure patient safety. The focus on patient safety is clear, as medications must be appropriately labeled and shipped. The government remains vigilant, overseeing these regulations to ensure compliance across the sector.

In many low- and middle-income countries (LMICs), including India, the regulatory framework governing e-pharmacies remains underdeveloped, and the absence of a physical infrastructure further complicates oversight. This has led to a proliferation of rogue online pharmacies, which may outnumber legitimate ones. These unregulated platforms often dispense substandard, falsified, or counterfeit medicines due to inadequate monitoring of their supply chains. The distribution of such compromised medications can have serious health consequences, sometimes posing life-threatening risks to patients.⁶ A major concern with these illicit e-pharmacies is their ability to sell prescription medications, including Schedule H drugs, without requiring a valid prescription. This practice not only undermines medical supervision but also encourages self-medication among consumers⁷. The widespread availability of health-related information on the internet has further fueled this trend, as individuals increasingly attempt to self-diagnose and treat their ailments without professional guidance. The combination of easy access to potent medications and a lack of regulatory enforcement creates a dangerous situation, increasing the risk of adverse drug reactions, antibiotic resistance, and potential drug dependencies. Addressing this issue requires stricter enforcement of regulations, improved tracking of e-pharmacy supply chains, and greater public awareness about the risks associated with purchasing medications from unverified online sources.

⁶ Mackey TK, Nayyar G. Digital danger: A Review of the Global Public Health, Patient Safety and Cybersecurity threats posed by illicit online pharmacies. *Br Med Bull.* 2016;118(1)110-126

⁷ Crawford SY. Internet pharmacy: Issues of access, quality, costs, and regulation. *J Med Syst.* 2003:27

CONCLUSION

Back in 2018, the government rolled out some regulations through the Drugs and Cosmetics (D&C) Amendment Rules, but that framework is still in flux. It doesn't really capture all the intricacies of online pharmacies, like cross-state operations and data security challenges. There's no specific law that focuses purely on e-pharmacies; instead, current regulations cover the broader healthcare and pharmaceutical sectors, leaving e-pharmacies under general guidelines. This has created a bit of confusion, as many e-pharmacies are uncertain about their legal status and the precise rules they need to adhere to. Even when regulations are in place, enforcing them is a tough nut to crack. E-pharmacies often operate across state borders, making consistent compliance monitoring quite tricky. Making sure e-pharmacies verify prescriptions, uphold quality standards, and safeguard patient data demands a lot of resources and careful coordination between various regulatory bodies. In many instances, the enforcement of these regulations is either weak or not consistently applied. The legal and regulatory landscape surrounding online pharmacies in India is still up in the air, leaving the entire industry in a bit of a grey area. Nearly six years have passed since the South Chemists & Distributors Association (SCDA) first took a stand against online medicine sales in the Delhi High Court, yet the government hasn't managed to nail down a clear policy. In 2018, the court ordered a pause on the sale of unlicensed medicines online, and by early 2019, it instructed the government to establish a complete regulatory framework for this expanding sector. However, as of now, no such policy is in motion, leading to ongoing legal ambiguity and challenges for e-pharmacies.⁸

⁸ Regulation of e-pharmacies: An analytical study of existence and evolution by - Harshita Kakar & Rajveer Gurdatta (2022) IJALR, Available at: <https://ijalr.in/volume-1/issue-1/regulation-of-e-pharmacies-an-analytical-study-of-existence-and-evolution-by-harshita-kakar-rajveer-gurdatta> (Accessed: 10 September 2024).