


Online Pharmacies in India and 3 massive problems!

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Online pharmacies in India are becoming more prominent. During the pandemic, 8.8 million of the roughly 300 million households procured medicines through e-pharmacies, compared to 3.5 million in the pre-COVID-19 phase. Players like Reliance, Amazon, Practo, Flipkart, Apollo, PharmEasy, and Tata Group are expanding at a higher rate. The availability of prescription medicines – a new trend – propelled its popularity as well. All of this warrants a thorough analysis of the workings of the industry, the demand, the laws and all the problems that the consumers face.

The way the industry functions:

There are two main business models used by e-pharmacies in India: inventory-based and marketplace-based.

The inventory-based model is based on the ownership of medicine inventory. In this model, the warehousing operations of online pharmacies are integrated with carry and forwarding agents (professionals responsible for the transportation, distribution and storage of products), which serve as the pharmaceutical industry's first line of defence.

The marketplace-based business model – preferred by a significant section of the online pharmacy sector in India, is a model where online pharmacies serve as a technological middleman (aggregators) between buyers and sellers. The aggregator links customers and registered pharmacies to facilitate direct medication delivery through licensed chemists.

Recently, players are pushing traditional pharmacies toward an “omnichannel experience”. The term omnichannel refers to a customer experience that includes multiple offline and online channels and events when purchasing medications (from ordering the medicines to delivering them in person directly to the consumer).

Players & Strategies implemented:

Reliance & Netmeds:

Reliance, which acquired a majority stake in Netmeds, is using an omnichannel approach to remain viable in the pharmaceutical market with its rivals.

It is expanding its customer base by offering a diverse range of traditional pharmaceuticals as well as alternative medicines such as *Ayurveda* (the foundation of *Ayurveda* is the belief that illness results from an imbalance in an individual's body, mind, or consciousness. It is made up from a variety of plants, metals, minerals and animals.); *Unani* (in *Unani* medicine, maintaining health and preventing illness are prioritised over



receiving treatment. Herbs, minerals, and other naturally occurring materials are used to make Unani medicine) and Homeopathy (these are prepared using plants, animals, metals and even snake venom).

In addition to the various medications, it is expanding its accessibility by utilizing Reliance-Retail's extensive network of 1,000

shop-in-shop pharmacies across Reliance Smart Point stores. In today's digital age, the company has implemented an AI-based solution that will regulate the maximum order limit and ensure proper medication distribution. Netmeds provides mobile apps with functionality in regional languages, focusing on Tier-1, Tier-2, and Tier-3. The company employs information analysis for forecasting inventory management and ensuring the availability of necessary medications.

PharmEasy & Medlife:

Another industry player is PharmEasy, which acquired Medlife. It operates in 710 Indian cities and in 98% of pin codes. It continues to grow in addition to its online platform by opening physical stores. It has a competitive price because it offers a wide range of medical supplies and treatments, including over-the-counter drugs, diagnostic tests, and healthcare equipment, and it frequently competes with neighbouring pharmacies in the customer's vicinity.



PharmEasy's TV commercials and advertisements are one of the company's unique marketing strategies for engaging more customers. Meme promotional activities, sponsorships, SMS, email marketing, dance campaigns, and other initiatives have greatly aided PharmEasy in establishing trust and building a strong consumer base. Along with contributing to making medicines readily available, it aimed to transform the healthcare sector by providing patients and healthcare professionals with accurate details, making healthcare facilities more affordable, combating the critical issue of counterfeit medicines, and so on.

Tata 1mg:



According to reports from September 2023, the Tata Group, which recently purchased 65% of online pharmacy 1mg, will overtake PharmEasy's market share. While primarily an online platform, 1mg plans to establish physical stores, enabling consumers to buy pharmaceuticals in person and maintain its presence on the internet. This investment in 1mg contributes to Tata's ability to give customers superior customer experience and high-quality healthcare products and services. Tata Digital said 1mg has three cutting-edge testing labs and a supply chain that covers 20,000 pin codes across the country.

The Laws:

The *Drug and Cosmetics Act, 1940* read with the *Drug and Cosmetic Rules, 1945* along with the *Pharmacy Act of 1948* regulates the pharmaceutical sector in India.

| There's no exclusive and explicit law that governs online Pharmacies

No law validates the operation of online pharmacies, nor does any law make it an illegal practice. There existed a lack of proper guidelines and regulations in this e-industry. In 2018, the Government of India disseminated a draft amendment to the existing *Drugs and Cosmetics Rules 1945*, the amendments proposed were:

1. Every e-pharmacy company must mandatorily obtain a license from the Central Licensing Authority acquired from an online portal authorized by the government of India.
2. This amendment requires e-pharmacy companies to provide prescriptions within a specific time period as and when ordered thereby maintaining the records of the purchase.



3. E- Pharmacies must protect the confidential information of their patients and store the data with them to ensure non-infringement of privacy of the customers. These data can only be taken by the official authorities and shall be stored within this country.
4. Medicines and drugs mentioned under Schedule X of the said Act are strictly prohibited for sale, like Morphine, secobarbital, glutethimide, and narcotics, tranquilizers or psychopathic substances.
5. These rules authorise the central and state authority for inspection every two years.
6. Until these rules are enforced, online pharmacies shall operate according to the rules proposed for offline businesses.
7. If in case the customer feels that the quality of the medicine is compromised, they can complain to state regulators.

But these proposed amendments to the *Drugs and Cosmetics Rules, 1945* are not yet enforced.

The government released a draft of the *New Drugs, Medical Devices and Cosmetics Bill, 2022*. The Bill included e-pharmacies in its purview. Online pharmacies will need to obtain a license in order to carry on with business as usual, in accordance with *Section 41(2)* of the draft Bill. Additional recommendations for e-pharmacies regulation are also included in the draft bill. If the bill is signed into law, online pharmacies would also not be allowed to sell medicines without a licence.

The DCGI announced implementation of a single window facility, which will make the operations of the Pharmacy easier on both the ends- online and offline. Furthermore, in December 2015, the Office of Drugs Controller General sent a notice to Drug Controllers in States and Union Territories, emphasizing that the D&C Rules apply to online drug sales as well. The notice also emphasized that the aforementioned rules' provisions must be adhered to in both online and offline drug sales. The announcement essentially cleared the path for e-pharmacies to be granted licenses.

The Problems:

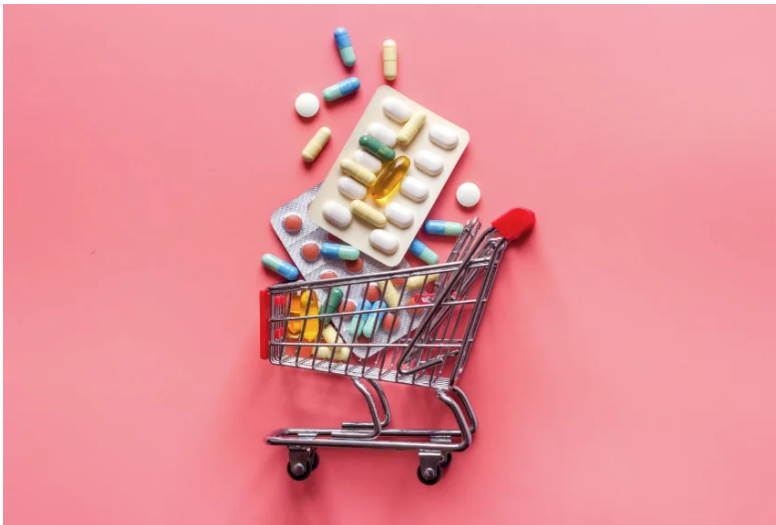
Licensing:

The overall market growth of the e-pharmacy sectors in India has been significantly impacted by the absence of appropriate rules and regulations, which has also deterred many significant investors. As a result, e-pharmacy companies can only function if they have a physical premise in India. The current *Drugs and Cosmetics Act, 1940* requires a pharmacist to have a valid license and a registered premise in order to safely store and sell the drugs.

On 08th February, 2023 the DCGI sent a show cause notice to 20 online pharmacies which included Tata 1mg, Flipkart, Practo, PharmEasy and Amazon, etc since these companies were operating without any license.

The DCGI cited the Delhi High Court's ruling in its notice, which enjoined these e-pharmacies from selling medicines online without a licence. The notice by DCGI also stated that e-pharmacies were discovered to be selling drugs online without a license even after the court order was issued. In response to the show cause notices, these online pharmacies responded to the Central Drugs Standards Control Organization (CDSCO), stating that they comply with the rules and regulations for selling drugs and medicines online. Since there is an absence of a definite set of rules that could regulate India's online pharmaceutical sector, the matter appears to be resolved.

Sale of Drugs:



A patient with a serious medical condition is unlikely to choose to buy medications online as they may consult a doctor in-person and purchase the medicines in the adjacent pharmacy. It is the patient that is unaware of whether their condition is serious or not and the patient that believes, knowingly or unknowingly, that their problem is not serious is at risk of trying to purchase medicines online.

For them, consultation & getting prescription medicines is an issue.

To avoid these issues, two practices emerged that allow the people who are purchasing medicines gain access to prescription medicines. Tele-consultation & Fake prescriptions.

Tele-consultation:

Not only are medications and prescriptions accessible online, but so are medical professionals. Physicians who offer teleconsultations (online facility for consulting with the doctors) are required to abide by the Telemedicine Guidelines. They can prescribe medicine online on their own discretion. Similar to the traditional in- person consultation (where patients visit the doctors personally), if the tele- consultants break any provision mentioned under the said guidelines, they run the risk of having their registration revoked. Thus, according to the said guidelines, a patient may file a complaint with the State Medical Council if they suffer from any professional misconduct. It entails the same professional accountability as that of a traditional in-person consultant.

There are a few categories of medicine which can be prescribed by registered medical practitioners online according to the guidelines.

List O doesn't require a prescription as they are medicines which are used for common conditions and are often available 'over the counter' (for instance, these medicines would include, paracetamol, etc); *List A* (these medications are those which can be prescribed during the first consult which is a video consultation and are being re-prescribed for refill, in case of follow-up); and *List B* (a list of medication which registered medical practitioner can



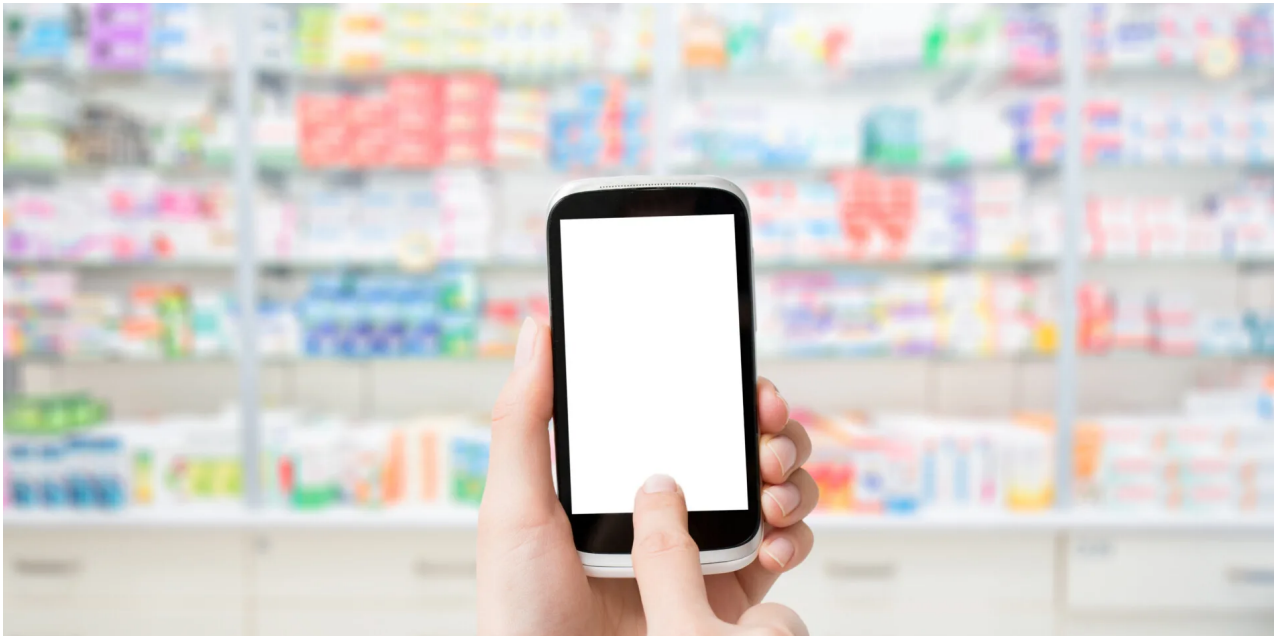
prescribe to a patient who is undergoing follow-up consultation in addition to those which have been prescribed during in-person consult for the same medical condition) are allowed to be prescribed through tele-consultation.

Fake Prescription:

Since it's not possible to thoroughly verify the credentials of a prescribing doctor or a diagnostic center, a prescription obtained through tele-consultation can be easily altered or manipulated. This is because there is no requirement for a digital signature to authenticate and verify the prescription submitted to the online pharmacies. Furthermore, while placing an order with an online pharmacy, there is no way to confirm that the same prescription is not being used more than once.

These two cause a major problem when it comes to medications classified under Schedule H and X of the *Drugs and Cosmetics Rules, 1945* – antibiotics and substances that can become addictions. Usually, these medicines can only be sold when a pharmacist is present and has a valid prescription in hand. But because there exists no physical check in online pharmacies, there exists a major problem of selling addictive drugs upon receipt of unchecked prescriptions and fake-prescriptions.

Drug abuse is one of the major issues in India among the youth. Drug abuse could possibly intensify manifolds by uploading a single prescription to several online pharmacies.



Inter-state sale:

Drugs that are legal in one state may not be considered legal in another due to the lack of well-established regulations governing the interstate sale of drugs. The laws governing the sale of drugs vary from state to state, which can cause confusion and possibly encourage illegal trade. Additionally, inconsistent enforcement of quality standards may lead to the interstate sale of fake or subpar pharmaceuticals.

A similar incident has already been reported to the Food and Drug Administration (FDA) in Mumbai where six people, including a medical drug agency, were arrested by police for allegedly manufacturing and distributing fake medications. The Food and Drug Administration (FDA) announced that it had taken down an interstate gang that sold fake medications.

Legal ambiguities that make enforcement and prosecution of illegal sales more difficult include conflicting laws and unclear jurisdiction. As such, careful oversight of the sources from which these medications are obtained or supplied will be a significant undertaking for this industry.

Conclusion

Online pharmacies are becoming increasingly popular due to its accessibility, cost, and convenience. They meet the growing demand for efficient healthcare solutions, especially in rural regions. However, there are responsibilities associated with this convenience. Managing the market's dysfunction becomes challenging since this industry lacks a clear set of regulations and guidelines.

Issues like licensing, the selling of certain prescription drugs categories, the provision of fake prescriptions, the accuracy of teleconsultations, patient's safety (in terms of authenticity of medicines & data) and the interstate distribution of illegal pharmaceuticals

are becoming more prevalent. Until these issues are adequately resolved, customers will not be able to take use of online pharmacies to the fullest extent possible.

There is an urgent necessity for robust frameworks with detailed guidelines for prescription validity, product quality, and user privacy. The delivery of healthcare supplies is changing dramatically with the advent of online pharmacies, but their success relies on establishing credibility, upholding strict quality standards, and guaranteeing ethical conduct.

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