

Regulating E-Pharmacy Sales in India

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ABSTRACT

Frequent adverts in periodicals and digital platforms encourage readers to acquire medications online by submitting doctor's prescriptions. Although this definitely reduces time and effort, most consumers of these online pharmacies are likely to be concerned about the authenticity, shelf life, and origin of the drugs that are being given. Currently, these internet-based pharmacies or e-pharmacy platforms function as an online marketplace or as an inventory model in accordance with the Information Technology Act, 2000 and the e-commerce regulations. This paper tries to analyse the present laws regulating e-pharmacies in India and the negatives of e-pharmacy in India.

Key words: e-pharmacy, law, online, regulation, drugs

INTRODUCTION:

E-pharmacies, generally, employ three distinct types of business strategies. The inventory model, in which e-pharmacies own medicinal products and offer them directly to consumers via their online store or mobile app; the marketplace approach, in which e-pharmacies act as both a platform and a middleman, connecting consumers with physical drugstores; and the hybrid strategy, which is a blend of both of these. Netmeds, Tata1mg, Medlife, and PharmEasy are a few illustrations of internet pharmacy (Rao, 2023).

Laws regulating e-pharmacies

The Drugs and Cosmetics Act, 1940 ("D&C Act"), along with the Drugs and Cosmetics Rules, 1945 ("D&C Rules"), and the Pharmacy Act, 1948 are the principal pieces of law controlling the manufacturing, sale, and dissemination of medications and cosmetics in India at the moment (Nilanjan Sen, 2023). Several measures in the D&C Act and Rules assure the standards and grade of the pharmaceuticals. Importantly, no one is allowed to produce for selling or distribution, (i) any pharmaceutical product other than under and in compliance with the terms of an issued permit, and/or (ii) any substance that is contaminated, misbranded, fake, or of a low standard.

If the aforementioned provisions are broken, there may be financial fines and jail time as penalties. In particular, retail sales of the medications listed in various Schedules of the D&C Rules are permitted

only upon proof of and compliance with a prescription issued by a licenced medical professional. Furthermore, medication can be dispensed only by a licenced chemist upon valid prescription from a licenced physician.

The Pharmacy Act 1948 was enacted with the objective "to regulate the profession of pharmacy" (India, 2023). The Office of Drugs Controller General issued a notice to the drug controllers in the states and union territories in December 2015. In that notice, it was stated that the D&C Rules would still apply to drug sales that occur online and offline and that compliance with the rules would be required in both cases. In essence, the notice made it possible to provide licences for online pharmacies as well (Musyuni, 2023).

Laws governing e-pharmacies in India

A draft amendment by the Ministry of Health and Family Welfare vide its notification G.S.R. 817 (E) dated August 28, 2018 to the 1945 Drugs and Cosmetics Rules was released by the Ministry. The "sale of drugs by E-Pharmacy" chapter is proposed to be included in the rules. The word "e-pharmacy" has been added for the first time in the draft regulations, and it is defined as the business of distributing, selling, storing, exhibiting, or offering for sale pharmaceuticals through a web-based platform or any other digital medium. "Sale by way of e-pharmacy" refers to the selling of pharmaceuticals to hospitals, dispensaries, medical, educational, or research institutes, as well as to any other individual via retail sales conducted through e-pharmacy (Gupta, 2023).

Terms were additionally established for the procedure for applying and the validity of registration, as well as obligations placed on e-pharmacies which must be met in order to be registered, such as location, release of certain data, distribution and marketing procedures, etc. E-pharmacies are subject to certain limitations, such as the inability to promote their drugs for any purpose on TV, radio, online, in printed form, or any other form of media and special restriction has been placed on dealing in narcotic and psychotropic drugs as defined by the Narcotic Drugs and Psychotropic Substances Act, 1985, including tranquillizers, and drugs listed in Schedules of the Rules is prohibited. A mechanism for monitoring e-pharmacy and resolving complaints has also been put in place. In addition to the Consumer Protection Act of 2019, this mechanism gives people the ability to file a

complaint with the state drugs controller, if they suspect that sub-standard quality, fake, or counterfeited drugs are being supplied through e-pharmacy (Kartik Ganapathy, 2023).

Apart from the aforementioned, e-pharmacies and its site are subject to the provisions of the IT Act and its regulations besides the Consumer Protection (E-Commerce) Rules, 2020 ("E-Commerce Rules"). While the E-Commerce Rules provide a comprehensive list of responsibilities for e-commerce entities to comply with, in addition to the details that must be announced in the website, the IT Act and its regulations set forth the rules and standards for operating a web-portal.

Drawback in the proposed amendment

Although the proposed rules are a positive move, they fall short of meeting the challenges associated with operating internet pharmacies. The problem of outlawing internet pharmacies is one that many nations are grappling with as these businesses provide clients illicit medications in uncontrolled quantities without a valid prescription, sometimes in subpar or prohibited forms. Because these websites function covertly, it is very challenging to identify them and hold them accountable. Furthermore, the draft rules only provide for periodic inspections of pharmacies that are already registered and licence termination if standards are not followed.

The proposed Rules do not impose any obligation on websites that are not authentic, nor do they offer a method to deal with them. The legislators need to create a special department or give the Drugs Controller General of India more authority in order to: (1) locate and shut down illicit websites that sell medications; and (2) raise public knowledge of consumer rights. To discourage the establishment of illicit pharmacies, the draft rules must additionally contain a provision imposing accountability in the form of a fine or criminal prosecution.

According to the draft Rules, a prescription is a document from a licenced medical professional which can be written by hand or electronically made. Despite the fact that e-prescription is included in the Draft Rules, the policymakers have not fully addressed the matter. The new regulations emphasise that it is the duty of internet pharmacies to confirm the legitimacy of prescriptions. This method will not be totally successful, and customers should also be held accountable for providing fraudulent prescriptions or using the same prescription on many websites.

The regulation of lifestyle medications is another issue that the draft rules fail to acknowledge. There are now medications on the market that promise to help people lose weight, grow hair, cut back on their cravings for alcohol, cigarettes, and overeating, as

well as improve their lifestyle. These medications, also known as "lifestyle drugs," are typically available without a prescription and do not fall under the category of controlled substances. Even if lifestyle medicines cannot cause addiction, they can still be harmful to those who already have other health problems, hence laws are required to guarantee the safe and secure distribution of these drugs.

Other issues include:

Data privacy: Everyone is entitled to privacy as a fundamental right. However, the regulations now in place say nothing about how these e-pharmacies would handle patient personal data that they will have access to. Data is the new gold in today's society; thus, the government must make sure that it is not exploited.

Mechanism of regulation: The State licencing authorities oversee the registration of pharmacies and the selling of pharmaceuticals. On the other hand, e-pharmacies can operate across India after registering at a certain location. Thus, the question is raised as to how different State regulators will handle these online pharmacies. As a result, guidelines for the commercial operations of online pharmacies must be developed including inter-state sales.

Anti-competitive behaviour: Through their association, the All-India Organisation of Chemists & Druggists (AIOCD) and other traditional pharmacies are demonstrating against e-pharmacies, claiming that they are operating illegally and engaging in anti-competitive behaviour by giving customers steep discounts, which completely goes against the principles of a free market.

Present position of e-pharmacy regulation in India

Despite the fact that the Indian government has drafted new rules to change the D&C rules, they have not yet been notified in the official gazette and are awaiting implementation. In a number of petitions, the Hon. High Courts of Delhi and Madras requested that e-pharmacy activities be prohibited for the sake of the safety of the public. Both Honourable Courts supported outlawing the online sale of pharmaceuticals and medical supplies, and the Honourable High Court of Madras in *T.N. Chemists and Druggists Assn. v. Union of India* even went so far as to ask the government to enact new regulations governing the internet selling of medications. Furthermore, the Delhi High Court's December 2018 ruling in the *Zaheer Ahmed v. Union of India* case forbade the online sale of pharmaceuticals without a licence. The Drugs Controller General of India (DCGI) notified all drug controllers of this development in an official letter issued on November 28, 2019.

CONCLUSION

It is evident that the market for online pharmacies has already firmly established itself in the online medicine sales industry. Based on the numbers and overall situation, it appears that e-pharmacies are moving past the experimental stage and are starting to take shape. An actual illustration of this is how helpful e-pharmacies were during COVID-19. Furthermore, the law must evolve along with technology whenever it advances. Another contention is that because the marketplace-based e-pharmacies lack a pharmacist with a valid licence, they are unable to display drugs on their websites because the law only permits licence holders to do so. However, the marketplace model e-pharmacies contend that, in accordance with the Information Technology Act of 2000, they are merely intermediaries, linking buyers and sellers through their websites. The issue concerning if they may show pharmaceuticals on their website then comes up. The government must remove these barriers by making minor changes to the pre-independence era legislation. Rather than considering outright prohibiting e-pharmacies, the government should create a solid plan and provide precise regulations to deal with some of the present problems, such as fraudulent prescriptions, sales between states, etc.

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