Indian Journal of Medical Ethics Published online first on May 22, 2025

COMMENTARY

Emerging e-pharmacy sector in India: ethical and regulatory concerns

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Abstract

The rise of e-commerce has significantly broadened the marketplace, introducing greater convenience and accessibility to the desired products at the doorsteps of consumers. In recent years, even pharmacies have embraced the online platform. E-commerce plays a crucial role in providing technologically advanced healthcare services to all. While e-pharmacies provide numerous benefits, there are also inherent risks that can impact the health and well-being of patients. Since no legislation in India specifically deals with the e-pharmacy sector, they are governed by the existing legislation that regulates the pharmaceutical industry. This paper seeks to analyse challenges in regulating the e-pharmacy sector and to critically evaluate the applicability and effectiveness of the existing legislations in ensuring the safety and integrity of online pharmaceutical transactions in India.

Keywords: *e-commerce, e-pharmacy, advantages, challenges, effectiveness of existing legislation*

Introduction

A revolutionary change has been made in the healthcare sector with the emergence of e-pharmacies, which offer customers the delivery of medicines at their doorsteps. This is especially convenient for people in remote areas where the presence of retail pharmacies and specific medicines is limited [1]. They also provide some value-added services like e-consultation and e-symptomatic services in which the patient can communicate the symptoms to the healthcare providers through online platforms, particularly beneficial for elderly individuals and patients who need to travel long distances for consultations or do not have access to expert specialists [2]. Thus, e-pharmacies offer numerous benefits to enhance consumers' health.

The idea of selling medications outside the traditional brick-and-mortar pharmacies is not new. During the 1980s, in the United States (US), prescription drugs were delivered through mail orders, which evolved into online pharmacies. Conversely, e-pharmacies are recent entrants into the Indian e-commerce industry. They have grown rapidly during the Covid-19 pandemic with the increased demand for managing lifestyle disorders and chronic disease conditions. E-pharmacies operate using three distinct business models — i) the inventory model, where the e-pharmacy stores drugs and sells them directly to the customers through its website, ii) the marketplace model, where it acts as an intermediary, connecting the customer to a physical pharmacy, and iii) a combination of the inventory and marketplace models [3]. Netmeds, 1mg, Medlife, PharmEasy, etc, are some of the well-known e-pharmacies operating in India.

However, this convenient medium is currently facing some regulatory lacunae. No legislation in India specifically regulates e-pharmacies. Therefore, they must be regulated by the existing legislation that governs traditional pharmacies, mainly the Drugs and Cosmetic (D&C) Act, 1940, and Rules, 1945; the Pharmacy Act, 1948; the Pharmacy Practice Regulations, 2015, etc. Since the functioning of e-pharmacies is different from that of traditional pharmacies, there is ambiguity regarding the effectiveness of existing legislation. As the industry is growing rapidly, addressing regulatory issues is crucial in ensuring the delivery of quality healthcare services. Failure to do so will raise ethical concerns and adversely affect society's health as a whole. This paper aims to analyse the challenges raised by the e-pharmacy sector and also the effectiveness of existing legislation in regulating e-pharmacies in India.

Challenges in regulating the e-pharmacy sector in India

Proper storage and distribution

Medicines can be distributed only by registered pharmacists on the prescription of a medical practitioner [4: Sec 42]. However, with e-pharmacies, it is difficult to ascertain whether medicines are distributed by a registered pharmacist. Additionally, the law requires a pharmacy to have a registered premise for proper storage of medicines [5: Rule 64] and specifies the minimum equipment required for running a pharmacy [5: Schedule N]. Two scenarios are possible in the context of e-pharmacies. For the inventory model, the above requirements can be ascertained. However, it is hard to identify physical premises in the marketing model of e-pharmacies, where they only act as intermediaries. Furthermore, certain medications need specific storage conditions to maintain their quality and efficacy. The improper handling of medicines during transportation can also affect the quality of drugs and put people's health at risk. There is ambiguity regarding the conditions for registration and proper monitoring of storage and transportation of medicines with respect to e-pharmacies [6].

Another major challenge is that e-pharmacies distribute drugs to a customer based on the scanned copy of a prescription. Under the D&C Rules, the drugs specified in Schedule H and X can be sold only on the prescription of a registered medical practitioner, which should be in writing,

signed and dated. The pharmacist must make a note on the prescription stating that the drug has been supplied on a specific date [5: Rule 65]. However, these requirements are difficult to ensure for scanned copies of prescriptions, as shown in several recent cases.

A case was registered against Myra Medicines, an e-pharmacy app, following a complaint filed by Swadesh Seva Sanstha for selling Schedule H drugs and other medicines which were banned in the state without a valid prescription [7]. Later, in *Dr. Zaheer Ahmed v Union of India* [8], the petitioner filed this case after he came to know that one of his patients had purchased certain Schedule X drugs online, without a prescription. Similarly, many online pharmacies in the UK were found to be selling restricted drugs based only on completion of online questionnaires, without any proper checks [9].

The primary goal of placing these drugs on Schedules H or X is to control the overuse of medicines which may cause serious health issues. However, making these medications easily accessible through e-pharmacies negates this goal. Furthermore, the prescription can easily be manipulated and misused by individuals, by uploading one prescription several times on a website or using a single prescription on different websites, which increases the chance of self-medication and misuse of medicines, and it is difficult to verify the identity of the patient and the authenticity of prescriptions. Therefore, it is crucial to closely monitor the functioning of e-pharmacies to avoid the abuse of medicines.

Unclear liabilities of e-pharmacies as intermediaries

E-pharmacies can be classified as intermediaries, as defined in section 2(1)(w) of the Information Technology Act, 2000 as they provide medical services through an online platform [10]. Therefore, all obligations imposed on intermediaries by the Act, including those related to the authentication of electronic records, are also applicable to e-pharmacies. However, the law provides an exemption to intermediaries from being liable for any third-party information or data provided by the sellers [11: Sec 79] For instance, the Karnataka High Court affirmed this in a case where the online platform, Snapdeal, was accused of selling *Suhagra –100* (Sildenafil citrate tablets), a prescription drug included in Schedule H, without a licence, and ruled that Snapdeal could only be considered as an intermediary and not be held liable for drugs sold by third-party sellers using its platform [12].

In 2023, the Drugs Controller General of India (DCGI) issued a show-cause notice to 20 online sellers, including Amazon and Flipkart Health Plus, for engaging in the online sale of medicines without the required licence. Most of them claimed that they were only intermediaries and had no active role in dispensing the medicines. Under the guise of safe harbour protection, where legal immunity is provided to the online platforms against the data shared by their users, these platforms are still indulging in various illegal activities. Prescription drugs such as Cyclosporine, Sildenafil Citrate tablets, etc, are still available on these online platforms that function as intermediaries. This practice poses significant health risks, as improper dispensation of drugs can have life-threatening consequences. Why are online platforms such as Snapdeal, Amazon, Flipkart, etc, not liable for selling medicines without a licence as prescribed by the D&C Act? Intermediaries must be held fully liable, along with the sellers, to safeguard public health and safety. At the same time, there is also doubt about whether a marketplace like Snapdeal, Amazon, etc, can be considered as an e-pharmacy. This lack of clarity regarding the e-pharmacy sector underscores the need for further clarification and guidance in this evolving industry.

Presence of illegal online pharmacies

Illegal e-pharmacies distribute medicines without complying with national or international legal requirements. They often distribute substandard or counterfeit drugs, including those with misleading and deceptive brand names. This poses a significant threat to public health and safety and has become a global concern [13]. They also engage in selling unapproved drugs. The United States Food and Drug Administration issued warning letters to approximately 1050 websites worldwide and seized unapproved medications and medical devices that posed potential risks to patients [14]. Patients may turn to illegal e-pharmacies due to the convenience of getting prescription-only medicines without a valid prescription. This will promote self-medication, which sometimes leads to abuse or misuse of drugs, and poses serious risks to patients. Moreover, illicit e-pharmacy websites also sell prescription-only medicines through unlicensed individuals who lack proper training. People cannot verify whether the person dispensing the medicines is a trained pharmacist. This puts people who purchase medicines from these websites at risk of consuming unsafe or counterfeit products.

Moreover, the existing legislation fails to keep pace with rapidly advancing technology. Several illicit e-pharmacies operate from multiple websites, often from undisclosed locations, some managed by organised criminal networks, all of which are difficult to trace. The activities of illegal e-pharmacies violate legal and ethical medical standards, resulting in social, economic and psychological harm [15].

Inter-state sale of medicines

The law stipulates that pharmacies can sell medicines only within the jurisdiction of the licensing authority [4: Rule 59, 61, 62]. The regulations relating to interstate sale of medicine remain ambiguous. In the e-pharmacy sector, which consists of a large network of pharmacies integrated into a single platform, the interstate sale of medicines, especially the sale of banned drugs, poses a significant challenge. For instance, the Karnataka Drugs Controller registered a case against *Myra Medicines,* an online pharmacy app, for selling banned medicines in the state [7].

While ordering medicines through e-pharmacies, they may be supplied from another state. Due to the lack of regulatory oversight on interstate sale of medicines, there is a possibility that substandard medicines may be received by the customer. This can pose serious risks to the patient's health. Similar issues arise in the case of the international sale of medicine.

Currently, there is no global framework regulating e-pharmacies, resulting in limited international cooperation in this sector [16]. This may also lead to jurisdictional issues in claims under consumer protection cases [17], and international consumers may not get adequate protection against unethical practices. Therefore, the impact on consumers is unclear in cases where online pharmacies have centralised distribution networks and transport medications beyond State borders.

Right to privacy of patients

Sharing medical prescriptions with e-pharmacies could potentially involve greater risk of breach of privacy and confidentiality. All personal information entered on the website while ordering medicines online can be recorded, which may be accessed by third parties. The need for regulating such unauthorised access is the greatest legislative challenge. Issues regarding data privacy and security also arise in e-consultations, as patients share their sensitive personal data and medical history on these online platforms for effective communication with the doctor and accurate diagnosis. The safety of this information has to be protected technologically and legally. Legal regulations can introduce civil as well as criminal remedies for violation of privacy rights on e-pharmacy platforms. The most effective and expeditious remedy may be extended by consumer protection laws. As e-pharmacy platforms can be treated as electronic service providers, they undoubtedly fall within the domain of service as provided under the Consumer Protection Act, 2019 [18: Sec 2(7), Sec 2(17), Sec 2(42)].

Apart from legal remedies, technological safeguards preventing misuse of data on e-pharmacy platforms are of crucial importance. Online platforms are bound to protect the personal data of patients legally and ethically, mainly from theft or mishandling. Moreover, unsecured e-pharmacy platforms could constitute the primary grounds for violation of consumer rights. Consumer safeguards may be overruled by privacy policies of e-pharmacy platforms which may render terms and conditions that enable them to engage in limited transfer of data. An average citizen always acknowledges and expresses his willingness to transfer data. This may result in crucial impairment of their rights. Therefore, the role of the State in regulating e-pharmacies is vital in this regard.

The law relating to medical records in India is still in the infant stage. The public in India has very restricted access to medical records and due to the lack of proper laws, the ownership of medical records is also disputable. In this scenario, sharing medical records through electronic media will make public's rights to privacy and confidentiality more vulnerable. As many patients depend on online platforms for their healthcare needs, protecting the privacy and confidentiality of data is crucial.

The Digital Personal Data Protection Act, 2023 and patient data

In 2023, the Indian parliament passed the first legislation, The Digital Personal Data Protection (DPDP) Act, specifically dealing with personal data protection in India. Earlier, data were regulated by the Information Technology Act, 2000 and the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 (SPDI Rules). This Act aimed to regulate the processing of digital personal data and recognise the right of individuals to protect their own data. Nowadays, health data protection has become even more relevant due to the rise of e-pharmacy platforms. However, the Act neither expressly defines "health data" nor explicitly includes it within the definition of "personal data". However, personal data is defined as "any data about an individual who is identifiable by or in relation to such data". Therefore, medical records generated during e-consultations and electronic or scanned prescriptions provided by the medical practitioner can be considered as personal data as they include all the necessary information relating to that patient [19: Sec 2(t), Sec 2(h)]. Therefore, e-pharmacies can be considered as data fiduciaries [19: Sec 2(i)] and must comply with the provisions of the Act for collecting and processing personal data.

In the European Union, the General Data Protection Regulation distinctly specifies certain special categories of personal data as Sensitive Personal Data, including health data, which needs a higher level of protection [20: Article 9]. Similarly, the SPDI Rules and the Data Privacy and Protection Bill 2019 had given special emphasis to Sensitive Personal Data and had required higher protection for it than personal data. However, the DPDP Act in India does not mention the processing of Sensitive Personal Data. On the other hand, the Central Government may notify certain data fiduciaries as Significant Data Fiduciaries based on factors such as the volume and sensitivity of the data processed, the risk to the Data Principal, etc. These entities must appoint a Data Protection Officer to undertake periodic data protection impact assessment [19: Sec 10]. Since the criteria mentioned in the provisions for notifying the Significant Data Fiduciaries are vague, it depends on the discretion of the Central Government. Implementing strong regulatory measures and ensuring transparent privacy policies are essential for e-pharmacies to mitigate the risks involved in handling Sensitive Personal Data.

Recent developments

The Federation of Indian Chambers of Commerce and Industry, in 2016, released a "Self-regulation Code of Conduct" that requires the e-pharmacy sector to maintain

the highest professional standards and implement proper safeguards to ensure the health and safety of consumers [21]. The Union Government had also established an expert committee in 2015 to examine the issues of regulating the online sale of drugs and submitted the report in 2016. In 2018, a draft Rule titled "Sale of drugs by e-pharmacy" was introduced to bring e-pharmacies within the scope of the D&C Rules, 1945 [22]. It defines "e-pharmacy" and "e-pharmacy portal" and makes it mandatory for anyone who desires to store, distribute or sell medicines through an e-pharmacy portal to be registered with the Central Licensing Authority. The rule also prohibits the advertisement of any drug on the internet or any other media for any purpose. Additionally, the sale of tranquilisers, narcotic and psychotropic substances, and Schedule X drugs through e-pharmacies is strictly prohibited. The Central Licensing Authority can suspend or cancel the registration of e-pharmacies if they violate any provisions of the D&C Act or Section VI-B of the D&C Rules.

However, there are certain drawbacks to the new rule that need to be addressed. The Rule stipulates that the officer shall inspect the premises where the e-pharmacy business is conducted, every two years. This is quite inadequate. While considering the potential risk associated with improperly monitored e-pharmacies, it is necessary to inspect the premises at short intervals to ensure that medicines are stored in proper condition. Additionally, the Rule does not address the duties and liabilities of intermediaries involved in selling medicines through e-pharmacies, which is essential for ensuring compliance with regulations and safeguarding public health.

Even though initiatives have been attempted to regulate the e-pharmacy sector through specific rules, they have yet to be notified. Recently, the judiciary expressed concern about the regulatory challenges regarding e-pharmacies and stated that online sales of medicines should not be allowed until the D&C (Amendment) Rules, 2018, were notified [23]. However, the higher court stayed this order stating that a sudden prohibition on the online sale of medicines could lead to inconvenience and health issues for those who need medication. In 2022, a draft bill titled "Drug, Medical Devices and Cosmetics Bill, 2022" was introduced for regulating drugs and medical devices, aiming to replace the existing D&C Act. However, it does not explicitly address the regulation of e-pharmacies, and instead, makes it mandatory for every person who stocks, exhibits, sells, or distributes any drugs online to obtain a license from the appropriate authority [24]. The draft Bill requires the Central Government to create guidelines for e-pharmacies. The absence of proper legislation to regulate the online marketing of drugs has significantly impacted the whole e-pharmacy sector in India.

Conclusion

In today's digital age, consumers have increasingly turned to online markets, leaving behind traditional brick-and-mortar stores. The emergence of e-pharmacies makes it convenient for people to consult with medical professionals online and obtain essential medicines easily. At the same time, the illegal sale of medicinal products over the internet poses a serious threat to public health and safety, as falsified or substandard medicinal products can easily reach the public. Additionally, the sharing of patients' personal information through prescriptions or e-consultations poses a serious threat to their privacy and confidentiality. Therefore, sale of medicines through e-pharmacies should be well-regulated. This not only ensures the safety of consumers but also promotes trust in the e-pharmacy industry. The primary legislation that governs the sale of medicines in India, namely, the D&C Act, 1940 and the new Drugs, Medical Devices and Cosmetics Bill, 2022, do not explicitly mention the regulation of e-pharmacies. Even the draft D&C (Amendment) Rules, 2018, do not mention the liabilities of intermediaries, who play a vital role in the dispensing of medicine online through e-commerce platforms. Therefore, the need of the hour is to introduce a comprehensive legal framework to regulate the online supply of medicines and to have a system that balances the interests of public health with emerging technology.

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Conflict of Interest: None declared **Funding:** None

To cite: Haripriya G, Harigovind PC, Rakesh PS. Emerging e-pharmacy sector in India: ethical and regulatory concerns. *Indian J Med Ethics.* Published online first on May 22, 2025. DOI: 10.20529/IJME.2025.041

Submission received: August 12, 2024

Submission accepted: March 26, 2025

Manuscript Editor: Veena Johari

Peer Reviewers: Two anonymous reviewers

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